

EXHIBIT B

Page 1

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE
4 - - -

5 IN RE: VALSARTAN, LOSARTAN, : Honorable Renée
6 AND IRBESARTAN PRODUCTS : Marie Bumb
7 LIABILITY LITIGATION : District Court
8 : Judge
9 THIS DOCUMENT RELATES TO :
10 Gaston Roberts, et al. v. : Case No.
11 Zhejiang Huahai :
12 Pharmaceutical Co., et al. : 1:20-cv-00946-
13 : RMB-SAK
14

15 - - -
16 MAY 8, 2025
17 - - -

18 Remote Videotape Deposition,
19 taken via Zoom, of GREGORY DIETTE, Ph.D.,
20 commencing at 11:03 a.m., on the above
21 date, before Amanda Maslynsky-Miller,
22 Certified Realtime Reporter and Court
23 Reporter in and for the State of New
24 Jersey.

- - -

<p>Page 2</p> <p>1 APPEARANCES:</p> <p>2</p> <p>3 NIGH GOLDENBERG RASO & VAUGHN, PLLC</p> <p>4 BY: DANIEL NIGH, ESQUIRE</p> <p>5 BY: STEPHANIE IKEN, LAW CLERK</p> <p>6 1333 College Parkway</p> <p>7 #1049</p> <p>8 Gulf Breeze, Florida 32563</p> <p>9 (850) 600-8090</p> <p>10 dnigh@nighgoldenber.com</p> <p>11 siken@nighgoldenber.com</p> <p>12 Representing the Plaintiffs</p> <p>13</p> <p>14 KIRKLAND & ELLIS LLP</p> <p>15 BY: JESSICA DAVIDSON, P.C., ESQUIRE</p> <p>16 601 Lexington Avenue</p> <p>17 New York, New York 10022</p> <p>18 (212) 446-4800</p> <p>19 jessica.davidson@kirkland.com</p> <p>20 Representing the Defendant</p> <p>21</p> <p>22 GREENBERG TRAURIG LLP</p> <p>23 BY: STEVEN M. HARKINS, ESQUIRE</p> <p>24 Terminus 200</p> <p>3333 Piedmont Road NE</p> <p>Suite 2500</p> <p>Atlanta, Georgia 30305</p> <p>(678) 553-2100</p> <p>harkinss@gtlaw.com</p> <p>Representing the Defendants</p> <p>ALSO PRESENT:</p> <p>Bill Geigert, Videographer</p> <p>- - -</p>	<p>Page 4</p> <p>1 - - -</p> <p>2 DEPOSITION SUPPORT INDEX</p> <p>3 - - -</p> <p>4</p> <p>5 Direction to Witness Not to Answer</p> <p>6 Page Line Page Line Page Line</p> <p>7 None</p> <p>8</p> <p>9</p> <p>10 Request for Production of Documents</p> <p>11 Page Line Page Line Page Line</p> <p>12 None</p> <p>13</p> <p>14</p> <p>15 Stipulations</p> <p>16 Page Line Page Line Page Line</p> <p>17 5 1</p> <p>18</p> <p>19</p> <p>20 Question Marked</p> <p>21 Page Line Page Line Page Line</p> <p>22 None</p> <p>23</p> <p>24</p>
<p>Page 3</p> <p>1 - - -</p> <p>2 I N D E X</p> <p>3 - - -</p> <p>4</p> <p>5 Testimony of: GREGORY DIETTE, Ph.D.</p> <p>6 By Attorney Nigh 6</p> <p>7 By Attorney Davidson 154</p> <p>8</p> <p>9 - - -</p> <p>10 E X H I B I T S</p> <p>11 - - -</p> <p>12</p> <p>13 NO. DESCRIPTION PAGE</p> <p>14 No exhibits were marked.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 5</p> <p>1 - - -</p> <p>2 (It is hereby stipulated and</p> <p>3 agreed by and among counsel that</p> <p>4 sealing, filing and certification</p> <p>5 are waived; and that all</p> <p>6 objections, except as to the form</p> <p>7 of the question, will be reserved</p> <p>8 until the time of trial.)</p> <p>9 - - -</p> <p>10 VIDEO TECHNICIAN: Good</p> <p>11 morning. We are now on the</p> <p>12 record. My name is Bill Geigert.</p> <p>13 I'm a videographer for Golkow, a</p> <p>14 Veritext division. Today's date</p> <p>15 is May 8th, 2025. The time is</p> <p>16 11:03 a.m.</p> <p>17 This remote video deposition</p> <p>18 is being held in the matter of</p> <p>19 Valsartan, Losartan and Irbesartan</p> <p>20 Products Liability Litigation in</p> <p>21 the United States District Court</p> <p>22 for the District of New Jersey.</p> <p>23 The deponent is Dr. Gregory</p> <p>24 Diette.</p>

<p style="text-align: right;">Page 6</p> <p>1 All parties to this</p> <p>2 deposition are appearing remotely</p> <p>3 and have agreed to the witness</p> <p>4 being sworn in remotely.</p> <p>5 Due to the nature of remote</p> <p>6 reporting, please pause briefly</p> <p>7 before speaking even to ensure all</p> <p>8 parties are heard completely.</p> <p>9 All counsel will be noted on</p> <p>10 the stenographic record. The</p> <p>11 court reporter is Amanda Miller,</p> <p>12 and she will now swear in the</p> <p>13 witness.</p> <p>14 - - -</p> <p>15 GREGORY DIETTE, Ph.D., after</p> <p>16 having been duly sworn, was</p> <p>17 examined and testified as follows:</p> <p>18 - - -</p> <p>19 EXAMINATION</p> <p>20 - - -</p> <p>21 BY ATTORNEY NIGH:</p> <p>22 Q. Good morning, Doctor. Can</p> <p>23 you please state your name and spell your</p> <p>24 last name, please?</p>	<p style="text-align: right;">Page 8</p> <p>1 ATTORNEY DAVIDSON: So,</p> <p>2 sorry, Daniel. I'm not going to</p> <p>3 object a lot today. I want to be</p> <p>4 efficient.</p> <p>5 When you lean back, your</p> <p>6 voice becomes a little bit weak.</p> <p>7 And so it's, like, hard to hear</p> <p>8 you.</p> <p>9 ATTORNEY NIGH: Okay.</p> <p>10 ATTORNEY DAVIDSON: I don't</p> <p>11 know why. Something about your</p> <p>12 microphone. If you can just get,</p> <p>13 like, a little bit closer to your</p> <p>14 microphone.</p> <p>15 And, hopefully, you won't</p> <p>16 hear for me for a long time after</p> <p>17 this.</p> <p>18 ATTORNEY NIGH: Okay.</p> <p>19 BY ATTORNEY NIGH:</p> <p>20 Q. Doctor, when did you first</p> <p>21 start your work in this case?</p> <p>22 A. It was last calendar year.</p> <p>23 And I think it was approximately November</p> <p>24 or so of last year.</p>
<p style="text-align: right;">Page 7</p> <p>1 A. Sure. It's Gregory Diette,</p> <p>2 D-I-E-T-T-E.</p> <p>3 Q. And, Doctor, you have --</p> <p>4 you've been in many depositions, correct?</p> <p>5 A. I have.</p> <p>6 Q. Okay. I'll just go through</p> <p>7 a couple of the ground rules.</p> <p>8 First off, it's not an</p> <p>9 endurance test. If you need a break at</p> <p>10 any time, just let me know and we'll take</p> <p>11 a break, okay?</p> <p>12 A. Sure thing.</p> <p>13 Q. And, second, if I ask a</p> <p>14 question and you don't understand the</p> <p>15 question, just ask me to repeat it or I</p> <p>16 can rephrase it for you.</p> <p>17 But if you answer the</p> <p>18 question, I'm going to assume that you</p> <p>19 understood the question.</p> <p>20 Is that fair?</p> <p>21 A. It is fair.</p> <p>22 Q. Okay. Doctor, when did you</p> <p>23 first start your work in relation to this</p> <p>24 case?</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. Okay. And so November of</p> <p>2 2024?</p> <p>3 A. That's right.</p> <p>4 Q. And approximately how many</p> <p>5 hours have you worked on this case?</p> <p>6 A. I don't know if I'd have a</p> <p>7 good estimate. I can tell from -- like,</p> <p>8 I don't know, do you have any, like,</p> <p>9 invoices or anything?</p> <p>10 Q. Without looking at the</p> <p>11 invoices, do you have any sort of</p> <p>12 estimate?</p> <p>13 A. Not a good one. No, I</p> <p>14 think -- I mean, I think the invoices</p> <p>15 would be, you know, reasonably accurate</p> <p>16 at least for the -- you know, for the</p> <p>17 months that there's an invoice.</p> <p>18 Q. Do you believe that you've</p> <p>19 spent more than a total of 100 hours in</p> <p>20 this case?</p> <p>21 A. I don't think it's as much</p> <p>22 as that.</p> <p>23 Q. Do you think you've spent</p> <p>24 somewhere between 50 to 100 hours?</p>

<p style="text-align: right;">Page 10</p> <p>1 A. It would be in that range, 2 yes. 3 Q. And how much do you bill per 4 hour? 5 A. It's \$600 per hour. 6 Q. Okay. And, Doctor, I've 7 reviewed your report. And other than the 8 case caption, I don't see Mr. Roberts' 9 name anywhere in the report. 10 Does that sound accurate? 11 A. It does. 12 Q. Did you review Mr. Roberts' 13 medical records? 14 A. Not -- not in detail. I 15 received some, and I just -- I mostly 16 just skimmed a couple of places, I think 17 mostly, actually, in some of the other 18 expert reports, just to get the 19 general -- you know, my -- a general 20 understanding of what the case was about. 21 But I did not scrutinize his 22 medical records. 23 Q. Did you review any of his 24 prescription records?</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Oh, I think -- I'm sorry, 2 I -- I just listened to the tense. I 3 mean, you said did I, and I don't think 4 I've given any opinions yet. 5 So I just -- that's all. 6 I'm just trying to be literal. 7 I'd say there's one opinion 8 that might be specifically about him. 9 But otherwise, I would say they're all 10 general. 11 Q. And what is the one opinion 12 specific to him? 13 A. From looking at the 14 materials, I saw that, you know, 15 different experts estimated his latency 16 from the time of use of the 17 NDMA-contaminated valsartan to be about 18 1.86 years. And it seemed to me that the 19 latency was shorter than anything I could 20 find, you know, in the scientific 21 literature. 22 Q. So other than latency, did 23 you give any other opinions that are 24 specific to Mr. Roberts' case?</p>
<p style="text-align: right;">Page 11</p> <p>1 A. I did not. 2 Q. Did you review any of the 3 testimony of the treating doctors in this 4 case? 5 A. No. 6 Q. Did you review any of the 7 testimony of the prescribing doctors? 8 A. Isn't that the same thing? 9 Q. Treating, prescribing, 10 sometimes people call it the same thing. 11 A. I see. 12 Well, either way. So 13 neither one. 14 Q. Okay. And did you review 15 the transcript of his -- the deposition 16 transcript of his wife? 17 A. No. 18 Q. Okay. Did you give any 19 opinions today that are specific to 20 Mr. Roberts? 21 A. Not yet. 22 Q. Okay. Suffice it to say 23 your opinions are related to general 24 causation, correct?</p>	<p style="text-align: right;">Page 13</p> <p>1 A. I don't plan to. 2 Q. Doctor, in evaluating 3 epidemiological studies regarding toxic 4 substances, it's important that you 5 understand the characteristics of that 6 toxic substance, correct? 7 A. To a certain extent, yes. 8 Q. What research did you 9 undertake to try to understand NDMA? 10 A. Well, I looked at a variety 11 of sources. I mean, I'm somewhat 12 familiar with nitrosamines just from, you 13 know, having done some other work. 14 But for NDMA in particular, 15 it wasn't just one source. And I don't 16 know if I remember them all. 17 But it certainly included, 18 like, IARC monographs, you know, which 19 usually do a nice job of describing what 20 the -- the substance is. In, you know, 21 each of the epidemiological studies 22 there's usually a little bit of 23 information about what NDMA is as well. 24 I think there's an ATSDR document that</p>

<p style="text-align: right;">Page 14</p> <p>1 provides information about that as well. 2 I don't know if I'll think 3 on the spot of every single source. But, 4 you know, there's an oncology textbook 5 that I like and refer to. The Weinberg 6 textbook. And they describe it, as well, 7 in relationship to, you know, information 8 about potential carcinogens and so forth. 9 There may be other sources 10 as well. 11 Q. Did you review the general 12 causation reports submitted in the 13 valsartan case? 14 A. I guess can you be specific? 15 Because I don't know how many there were. 16 Q. Other than -- other than 17 Dr. Siddiqui's report, Dr. Zauer's report 18 and Dr. Bruce's report did you review any 19 other expert reports in this case? 20 A. So expert reports from 21 Dr. Mamood, I think. And I think -- that 22 seemed like it was more specific 23 causation, perhaps, but I think maybe 24 some general causation.</p>	<p style="text-align: right;">Page 16</p> <p>1 or not, particularly in the context of 2 humans. 3 Q. What is a complete 4 carcinogen? 5 A. You may get a different 6 answer from somebody whose, you know, 7 field is cancer biology. 8 But, to me, it's a 9 carcinogen that can either promote, 10 promote -- well, it can do both, it can 11 initiate and then also promote the 12 cancer. 13 Q. Have you reviewed materials 14 that suggest that NDMA can promote 15 cancers? 16 A. In humans. I mean, I looked 17 at the ATSDR statement. And, you know, 18 they looked at whether it was a genotoxic 19 agent, for example, and pointed out that 20 with the exception of one case report, 21 that there's not human studies. 22 So, you know, I don't -- I 23 don't know that -- otherwise that it is. 24 Q. Animal studies have shown</p>
<p style="text-align: right;">Page 15</p> <p>1 And then the one other 2 doctor. I don't know if I referred to it 3 in my report. There's another -- another 4 defense expert, the guy at Penn who is a 5 biologist. 6 Q. Did you review the report of 7 Dr. Panigraphy? 8 A. Can you say the name again? 9 I'm sorry. 10 Q. Panigraphy. 11 A. I may have seen it back 12 months ago, but I don't recall that. 13 Q. Did you review the report of 14 Dr. Etmanon? 15 A. Again, I couldn't quite hear 16 the name. 17 Q. Etmanon? 18 A. It doesn't sound familiar. 19 Q. Did you review the report of 20 Dr. Gibbs? 21 A. If I did, I don't recall. 22 Q. Doctor, NDMA is a complete 23 carcinogen, correct? 24 A. I don't know if that's true</p>	<p style="text-align: right;">Page 17</p> <p>1 that NDMA can act as a promoter in 2 animals, correct? 3 A. That's my understanding. 4 And that's without doing a deep dive into 5 the -- you know, each and every animal 6 study, but looking at other entities that 7 summarize that, such as ATSDR. 8 Q. Do you have any reason to 9 believe that the -- that if NDMA can act 10 as a promoter in animals that it can't 11 act as a promoter in humans? 12 A. I -- I can't say one way or 13 the other whether that would be true. 14 Q. What does it mean for a 15 carcinogen to act as a promoter? 16 A. Something that essentially 17 can encourage the growth of an existing 18 tumor. 19 Q. Doctor, have you reviewed 20 key characteristics of carcinogens? 21 A. Ever in my life? I'm sure. 22 Q. Do you know what the ten key 23 characteristics of carcinogens are? Does 24 that sound familiar to you?</p>

<p style="text-align: right;">Page 18</p> <p>1 A. I know there's a list that 2 IARC uses, and I don't know if it's the 3 same one. If it is the same list, then 4 I've seen them at one time. But I can't 5 recite them. 6 Q. Have you evaluated or 7 considered any materials that look at the 8 key characteristics of NDMA? 9 A. I have not. 10 Q. Doctor, in toxicology have 11 you heard of the adage that dose makes 12 the poison? 13 A. Of course. 14 Q. And what does that mean? 15 A. Well, that -- it means a 16 couple of things. I think, you know, 17 sometimes people use that to refer to 18 something more along the lines of dose 19 response. 20 But I think the more general 21 meaning is that, you know, virtually any 22 substance can be toxic at a sufficient 23 dose, at some high dose. 24 And so it refers to the fact</p>	<p style="text-align: right;">Page 20</p> <p>1 But, again, I could -- I 2 could read it again. It's in some of the 3 documents I've looked at. But I have not 4 made any effort to commit it to memory. 5 Q. Have you looked at the 6 amount of NDMA that's in ranitidine? 7 A. No, same -- same issue. 8 I've seen, you know, writings about it. 9 But I've not tried to commit it to 10 memory. 11 Q. Do you know the amount of 12 NDMA that's in nizatidine? 13 A. I have no idea. 14 Q. Have you looked to compare 15 the amount of NDMA that's in nizatidine 16 versus the amount of NDMA that's in 17 ranitidine? 18 A. No. I can't imagine what 19 purpose it would serve me. But I 20 certainly haven't done it. 21 Q. Have you looked to compare 22 the amount of NDMA that's in nizatidine 23 compared to the amount of NDMA that's in 24 valsartan?</p>
<p style="text-align: right;">Page 19</p> <p>1 that -- you know, that a substance that 2 can cause, you know, harm, for example, 3 at a high dose doesn't necessarily cause 4 it at a low dose. 5 Q. Doctor, do you know the 6 amount of NDMA that was in valsartan 7 pills? 8 A. No. I read different 9 information about it from different 10 expert reports. But I don't have an 11 opinion about what it is. 12 Q. Can you describe the amount 13 of NDMA that was in Mr. Roberts' pills? 14 A. No. I mean, I could 15 certainly, you know, reread the portions 16 of different expert reports that 17 articulated that. 18 But I haven't tried to 19 commit that to memory. 20 Q. Can you describe the amount 21 of NDMA that are in valsartan pills in 22 general? 23 A. I think that's what I was 24 answering in the question before.</p>	<p style="text-align: right;">Page 21</p> <p>1 A. I haven't tried to compare 2 the amount of NDMA in any two different, 3 you know, pills or products. 4 Q. My next question is, have 5 you attempted to compare the amount of 6 NDMA that's in ranitidine versus the 7 amount of NDMA that's in valsartan? 8 A. No. I mean, same answer. 9 I mean, I haven't -- haven't made any 10 effort to try to compare, you know, 11 different types of pills. 12 Q. Doctor, have you -- you 13 mentioned in your report an unpublished 14 study. 15 Do you recall that? 16 A. The Lee study? 17 Q. Yes. 18 A. Yes, I do. 19 Q. And did you only review the 20 abstract for that study? 21 A. No, there's a -- there's a 22 preprint that's available online. So 23 there's both, like, an abstract and, 24 like, a -- you know, it sort of has the</p>

<p style="text-align: right;">Page 22</p> <p>1 format of a full-fledged manuscript and 2 so forth. 3 But it's a -- it's, like, a 4 preprint, I think they call it, that has 5 not gone through peer review. 6 Q. Did you notice any 7 differences between the preprint and the 8 abstract? 9 A. Well, the abstract I saw was 10 tiny. I mean, there's, like, so much 11 more information in the -- in the, you 12 know, manuscript version of it. 13 Q. Did you notice any 14 differences in the preprint manuscript 15 that conflicted with the information 16 provided in the abstract? 17 A. I don't recall that. 18 Q. Did you -- did you look to 19 compare those two sources to see if they 20 had conflicting information? 21 A. Well, no, I didn't hold them 22 side by side. I read them each and just 23 tried to glean what information each one 24 had.</p>	<p style="text-align: right;">Page 24</p> <p>1 really, the meat of what I would have 2 available to me for understanding the 3 epidemiologic evidence on a topic, you 4 know, would come through the peer-review 5 publication, you know, pipeline. 6 And so far these have not 7 gone through that. 8 Q. Have you looked to -- or, 9 sorry. Strike that. 10 Do you know whether or not 11 the Lee paper was submitted in peer 12 review? 13 A. There's no information about 14 that. 15 Q. Okay. 16 A. At least not available to 17 me. 18 But -- I'm sorry, I'm 19 just -- I'm just trying to say, yeah, 20 so I don't -- I don't have any idea, 21 like, whether it's been submitted. 22 Q. Doctor, did you look or rely 23 upon any abstracts for the ranitidine 24 studies that you looked at?</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. When you gave your opinions, 2 did you rely on the abstract or did you 3 rely on the preprint? 4 A. So I think the preprint has, 5 like, a -- sort of a more fulsome 6 description of what the methods are and 7 certainly, you know, have more results 8 and they have a -- you know, a discussion 9 section that's longer. 10 It's -- you know, I don't 11 put a lot of stock in either because 12 they're not peer reviewed. You know, 13 they're just something that exists in the 14 world. 15 So I didn't really compare 16 the weight of one or the other. But the 17 one that has more information certainly 18 has more information. 19 Q. And when you say you don't 20 put a lot of "stock in either," what do 21 you mean by that? 22 A. Oh, because -- because these 23 aren't part of the peer-review 24 literature, right. So to me -- to me,</p>	<p style="text-align: right;">Page 25</p> <p>1 A. And I guess by 2 "abstracts" -- I just -- I just want to 3 make it clear, it's not a big deal, but 4 almost all the peer-review papers have a 5 section called the abstract, right. So 6 the abstract is kind of baked into a lot 7 of those. 8 I don't -- I don't recall 9 that there were any that were just simply 10 conference proceedings in that sort of 11 abstract. 12 Q. Did you rely on any 13 unpublished studies in regards to 14 ranitidine? 15 A. I don't believe so. 16 Q. Do you know if there were 17 any? 18 A. I'm not aware. 19 Q. Did you search for those? 20 A. Well, I searched for 21 ranitidine studies, and nothing else 22 popped up other than what I -- you know, 23 then what I've provided, you know, in my 24 report.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q. Doctor, did you evaluate 2 potential bias of any of the studies that 3 you cited? 4 A. Of course. 5 Q. And which studies that you 6 cited to had potential conflicts of 7 interest? 8 A. Oh, that kind of bias? 9 Q. Yes. 10 A. Because bias is an 11 epidemiologic term, right. So when I 12 answered your question yes, I was talking 13 about biases meaning, like, selection 14 bias, issues with confounding, you know, 15 other -- other sorts of bias. 16 In terms of conflicts of 17 interest, I read that in every paper. 18 But I didn't -- I didn't store, like, a 19 memory of, you know, which ones did or 20 didn't report a conflict of interest. 21 Q. Do you know if any of the 22 studies that you cited to reported 23 conflicts of interest? 24 A. I'd have to look at each and</p>	<p style="text-align: right;">Page 28</p> <p>1 for you to know what happened to them, 2 you know, that's an issue. 3 The length of time, which 4 for cancer studies, assuming that there's 5 an exposure of interest and the outcome 6 is cancer, then it would get into the 7 issues of latency. And that would be 8 important as well. 9 Q. In terms of cancer and the 10 length of time, why would it be important 11 to evaluate the amount of follow-up 12 included in the study? 13 A. So for the length of time, 14 you know, if it's known or suspected what 15 the latency is between the timing of an 16 exposure and the outcome, meaning, like, 17 the incidence or the diagnosis of cancer, 18 it would be important to have a 19 sufficient amount of time go by in order 20 to find that -- that relationship. 21 Q. In order to know the true 22 effect or the true point estimate that a 23 carcinogen would have on cancer, is it 24 true that it would be important to have</p>
<p style="text-align: right;">Page 27</p> <p>1 every one. I just don't recall. 2 Q. Do you recall whether or not 3 any of the studies were -- that you cited 4 to were published by manufacturers of -- 5 sorry. Strike that. 6 Doctor, when you look at 7 studies, why is it important to evaluate 8 the amount of follow-up that's included 9 in studies where -- when they're looking 10 at cancer? 11 A. So the "amount of follow-up" 12 is a little bit vague. But I'll just 13 tell you how I would -- I would tackle 14 that and you can please just tell me if 15 that's not what you were after. 16 Because the amount can mean 17 the length of time, for example. It can 18 also mean the proportion of people that 19 entered the study that also provided data 20 at follow-up time periods. 21 And so, you know, each of 22 those is an important concept, right. If 23 you start a study and, you know, 24 90 percent of the people aren't available</p>	<p style="text-align: right;">Page 29</p> <p>1 follow-up for decades? 2 A. Well, it could include 3 decades. It wouldn't automatically have 4 to include, you know, decades for every 5 single sort of cancer. 6 You know, for example, you 7 know, some of the cancers, like leukemia, 8 on average have much shorter latencies. 9 And so, obviously, you could 10 learn more information from a study that 11 had decades of follow-up, but it wouldn't 12 be necessary, you know, in order to learn 13 some information. 14 Q. Other than blood cancers, 15 would it be important to have decades of 16 follow-up in order to assess the true 17 point estimates for cancer-related 18 carcinogens? 19 A. I think so. I mean, it's -- 20 you know, so part of it is -- just one of 21 the issues is, I think, for many cancers 22 it's not known what the latency is. 23 And latency is also very 24 specific, right. So the latency between</p>

<p style="text-align: right;">Page 30</p> <p>1 one exposure may not be the same latency 2 between a different exposure and that 3 same cancer. 4 So, you know, if there's 5 knowledge about what that latency is in 6 any of those conditions, you would at 7 least want there to be enough time to go 8 by for that -- for that latency to be 9 reflected. 10 You know, decades would be 11 better. I mean, decades is always 12 better, right, in terms of just being 13 able to have more information. 14 Q. Doctor, in terms of latency, 15 the latency in a general population is a 16 different -- different analysis than the 17 latency than any individual person can 18 have in terms of getting cancer, correct? 19 ATTORNEY DAVIDSON: I'm 20 sorry. I'm going to object, 21 because I didn't understand the 22 question. Can you restate? 23 THE WITNESS: I was going to 24 say, I didn't quite understand</p>	<p style="text-align: right;">Page 32</p> <p>1 latency. 2 BY ATTORNEY NIGH: 3 Q. And in a population of 4 people, there can be a median time for 5 latency, correct? 6 A. Exactly. 7 Q. And then there can be a one 8 standard deviation out from that median, 9 correct? 10 A. True. 11 Q. There can be two standard 12 deviations out from that median, correct? 13 A. Well, there can be any 14 distribution around that median. But, 15 yeah. 16 But it includes, you know, 17 math that you could do along that -- 18 along those lines, too. 19 Q. So when you're discussing 20 latency and cancer, there could be a 21 whole distribution in terms of how long 22 it takes for people to get cancer, 23 correct? 24 A. Of course.</p>
<p style="text-align: right;">Page 31</p> <p>1 either. I apologize. 2 BY ATTORNEY NIGH: 3 Q. Doctor, in understanding the 4 latency in a population, that is a 5 different analysis than the latency that 6 an individual can have, correct? 7 ATTORNEY DAVIDSON: Still 8 going to object to the question as 9 vague. 10 THE WITNESS: Yeah, I'll 11 take a crack at it. I mean, I 12 guess, I mean, a population study 13 if it's designed properly could 14 give you information on what the 15 average or range of latencies is 16 that can occur in human beings, 17 you know, between the exposure and 18 the development or the recognition 19 of that cancer. 20 For an individual, you could 21 calculate it. But if you wanted 22 to understand it, it would make 23 sense to relate that to what the 24 population-based evidence is for</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. And some people can get 2 cancer much quicker than the median and 3 some people can get it much longer than 4 the median, correct? 5 A. I don't know. I mean, I 6 would have to consider cancer by cancer 7 and what the evidence is. 8 But certainly there can be a 9 range that includes shorter periods and 10 longer periods. 11 Q. For liver cancer, have you 12 considered what the first standard 13 deviation would be for latency -- 14 A. I haven't -- 15 Q. -- in a population? 16 A. So I haven't tried to do it 17 for a standard deviation. I've tried to 18 look and see, you know, what's been 19 published, which is not much on latency. 20 First of all, I don't find 21 anything on latency between 22 NDMA-contaminated valsartan and liver 23 cancer. So that I can't answer. 24 You know, there's -- there's</p>

<p style="text-align: right;">Page 34</p> <p>1 information about vinyl chloride that 2 looks like it's about 12 years would be 3 the typical distribution. 4 And then, if you'll see, I 5 cited a -- an article, or at least a 6 statement from the CDC, you know, where 7 they were trying to decide who could be 8 compensated for illnesses that could have 9 resulted from participating in the 9/11, 10 you know, cleanup and so forth. And, you 11 know, they -- they cited that 12 year. 12 They also cited an article 13 where someone had tried to create a 14 distribution of, like, basically, the 15 ranges of cancers that are solid cancers. 16 And in particular, they came 17 up with an estimate -- I think it was, 18 like, about -- it was, like, 10.68 or 19 something, it was -- approximately, like, 20 11 years in general from that. 21 And then I think overall 22 they said that they cited to -- I think 23 it was about, like, 6.8 to, like, 65 or 24 some really long number for solid cancers</p>	<p style="text-align: right;">Page 36</p> <p>1 idea what the distribution curve looks 2 like for liver cancer in terms of 3 latency? 4 A. No, I don't. I looked to 5 see what the -- what the reported latency 6 was. And so, you know, what they 7 reported was 12 years by citing the 8 article in that World Trade Center 9 document. And then for a different 10 author, they cited the nearly 11 -- 11 11 year. 12 Q. And that 12 years and the 13 11 years, that's the average time in 14 terms of latency for liver cancer, 15 correct? 16 A. For liver. 17 But they gave a range. So 18 not -- not a distribution around one 19 median, but they gave a range of 20 latencies for solid cancers in general. 21 And I'd have to look back to get the 22 exact number, but it was something like 23 6.8 all the way up to, like, 50 or 60 24 years.</p>
<p style="text-align: right;">Page 35</p> <p>1 more generally, you know, that wouldn't 2 be specific to liver cancer. 3 So that was the kind of 4 information I was able to find. 5 Q. For vinyl chloride, were you 6 able to find what the one standard 7 deviation would be in latency? 8 A. You know, I don't know if 9 that's in the -- in the document. But I 10 certainly didn't memorize it if it is. 11 Q. Did you look to see, for 12 vinyl chloride, what two standard 13 deviations was for latency in liver 14 cancer? 15 A. I can't tell you anything 16 about the distribution in terms of these 17 questions in terms of standard 18 deviations. 19 And, you know, to be frank, 20 I don't even know if it's a bell-shaped 21 curve, which would somehow fit into the 22 standard deviation idea that we're 23 discussing. 24 Q. Did you -- do you have any</p>	<p style="text-align: right;">Page 37</p> <p>1 So that was -- 2 Q. Do you recall -- sorry, go 3 ahead. I didn't realize you weren't 4 done. 5 A. No. That's okay. 6 So that was the range of 7 latencies that they were reporting. 8 Q. And that range of latencies, 9 do you recall the percentiles that they 10 were reporting? 11 A. I don't know what that 12 means. 13 Q. Well, the top -- was it the 14 25 percent, 75 percentile, in that range 15 that they reported? 16 A. I don't think that's the way 17 that they reported it. 18 I think -- I think they 19 were -- well, what they were after, 20 right, was the range of plausible 21 latencies. You know, they weren't -- 22 this wasn't an exercise in plotting 23 distributions, right. 24 The idea was, who's going to</p>

<p style="text-align: right;">Page 38</p> <p>1 get compensated for a tumor, right. And 2 so they -- they used the information they 3 could find for the few tumors where it 4 was available to see what the range of 5 plausible -- what the range of plausible 6 latencies was. 7 And then they chose four for 8 solid tumors. And I think, although they 9 didn't articulate it, it seemed to be 10 that was an effort to try to, you know, 11 if anything, err on the low side so that 12 people would get compensated from the 13 World Trade Center fund. 14 Q. Right. And that range of 15 plausible plausibility, do you know what 16 that range covered? Do you think that it 17 covered the entire distribution of 18 latency that they looked at? 19 A. I think it likely would, 20 from the way that they wrote that 21 statement. 22 Q. Okay. So you don't believe 23 that that range of distribution that they 24 were looking at was looking at a</p>	<p style="text-align: right;">Page 40</p> <p>1 A. I wouldn't -- I wouldn't 2 know where to begin to do what you're 3 asking. 4 Q. Did you compare the 5 aggressiveness of NDMA, in terms of 6 initiating and promoting tumors, versus 7 the aggressiveness of the carcinogens 8 that were involved in the World Trade 9 Center? 10 A. Everything we're talking 11 about is about human beings. And I'm not 12 aware of studies that document something 13 that's so-called aggressiveness for NDMA 14 and liver cancer. 15 Q. Did you compare the 16 aggressiveness of NDMA in initiating and 17 promoting tumors in animal studies versus 18 the aggressiveness of the carcinogens 19 that were involved in the World Trade 20 Center in animal studies? 21 A. So I don't know if 22 aggressiveness is a technical term. 23 But in any case, I mean, if 24 we're talking about looking at</p>
<p style="text-align: right;">Page 39</p> <p>1 percentile or only a portion of cancers 2 in the center of the distribution? 3 A. I'm not aware that that 4 happened. And it wouldn't make sense, 5 you know, given the exercise that they 6 were -- that they were performing. 7 Because they were trying to 8 make sure, you know, that they didn't 9 fail to compensate people who had a 10 plausible latency. Really, that's what 11 the exercise is about. 12 Q. Did you compare the 13 differences in the key characteristics of 14 NDMA versus the key characteristics of 15 the carcinogens that were involved in the 16 World Trade Center? 17 A. I don't -- I don't know how 18 to do that. I mean, how do you compare 19 them? 20 Q. Did you compare the key 21 characteristics between NDMA with animal 22 studies and the key characteristics of 23 the carcinogens in animal studies for the 24 World Trade Center?</p>	<p style="text-align: right;">Page 41</p> <p>1 characteristics of animal studies, I 2 think that belongs to a different type of 3 scientist than myself. 4 Q. Okay. Did you review any of 5 the reports that looked at those 6 comparisons in this case? 7 A. In which comparisons? 8 Q. The comparisons between NDMA 9 and the carcinogens that were involved in 10 the World Trade Center? 11 A. I don't recall seeing 12 anything along those lines. 13 Q. Do you have any expert 14 reports or opinions that you can rely on 15 for that sort of exercise? 16 A. I don't think so. I mean, 17 if you pointed me to one and it's 18 something that I've read, I'd be happy to 19 reread it. But I don't -- I don't recall 20 seeing that. 21 Q. Doctor, the time or latency 22 can be different in humans depending on 23 the type of carcinogen, correct? 24 A. Yes, of course.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. Did you do anything to 2 understand or look to see how the time 3 may be different, in terms of latency, 4 for NDMA versus other carcinogens? 5 A. There's nothing to look at. 6 There are no studies of NDMA that show 7 what the latency is with liver cancer. 8 So there's literally nothing to examine. 9 Q. Did you look at animal 10 studies in any way for that information? 11 A. No. And that's a different 12 field. That's not -- I mean, you have 13 not asked me yet what kinds of 14 backgrounds I have and don't have. 15 But I think if you asked me 16 if I'm a toxicologist, which maybe you'll 17 get to, I'll tell you I'm not a 18 toxicologist. I don't do animal 19 research. 20 So there's a couple of -- a 21 couple of things that point to a 22 different type of expert that may have 23 the capacity to do that. I'm not sure if 24 they do. But that's not my capacity.</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Do you have any idea in 2 which animals they've measured latency 3 for NDMA? 4 A. No. I've read a little bit 5 of information that mostly comes from 6 other treatises. But I haven't made any 7 study of that. 8 Q. Doctor, you previously 9 explained loss of follow-up. 10 What does that mean? 11 A. In a cohort study, that 12 people who are enrolled at a particular 13 point in time -- and we're talking about 14 cohorts here, for the most part. 15 In a cohort study, it would 16 be people that either can't be located 17 or, for whatever reason, didn't 18 participate in the follow-up in the 19 study. 20 Q. In terms of loss of 21 follow-up, what are some of the 22 shortcomings when utilizing insurance 23 claims databases for epidemiological 24 studies?</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. So in terms of evaluating 2 NDMA versus the other carcinogens that 3 you looked at in terms of latency, you 4 wouldn't have any information to evaluate 5 those differences, correct? 6 A. There's nothing to look at 7 because there's no information about 8 latency in humans and NDMA. So there's 9 literally nothing to compare it with. 10 Q. You wouldn't be able to do 11 that comparison in terms of looking at 12 animal studies, correct? 13 A. I just -- I think I just 14 explained that that's not my capacity. 15 And it's -- and -- you know, 16 and, to be frank, you know, if we're 17 talking about rats, you know, rats aren't 18 humans. And so I don't know what that 19 would teach me. Rats don't live 70 20 years. They live two years, right. 21 So timing issues in rats, 22 you know, wouldn't really tell me in 23 particular much about what the human 24 experience is.</p>	<p style="text-align: right;">Page 45</p> <p>1 A. In terms of loss of 2 follow-up or was that more general about 3 the shortcomings? 4 Q. In terms of loss of 5 follow-up. 6 A. Well, I think they would be 7 generic, I mean, in the sense if there 8 were people that you couldn't ascertain 9 what their outcome was, you wouldn't have 10 information about them, at least up until 11 the point when they were lost to 12 follow-up. 13 You know, you would 14 certainly have information -- because 15 there's a stream of time going by, right, 16 from the initial moment that you create 17 the cohort concept, and then people can 18 contribute data for many years and then 19 maybe not contribute at the end of the 20 study. 21 So you -- you just wouldn't 22 have information, you know, one way or 23 the other, about their outcome. 24 Q. Doctor, in the United</p>

<p style="text-align: right;">Page 46</p> <p>1 States, insurance that people have is 2 oftentimes tied to their jobs, correct? 3 A. So there's -- employer-based 4 insurance is one -- one format. 5 Q. And if -- in the U.S., if 6 people switch jobs, they may switch 7 insurances as well, correct? 8 A. That's my understanding. 9 Q. One of the shortcomings in 10 utilizing claims -- insurance databases 11 in the United States, may be that when 12 people switch jobs, they would switch 13 insurances and then you would have loss 14 of follow-up in the studies, correct? 15 A. If that happens and there's 16 no other way to sort of, like, you know, 17 sort of bolt-on information from a 18 separate insurance database, like, 19 because it might be feasible. 20 But in general I agree. 21 Like, for whatever reason, whether it's 22 switching jobs or, you know, that there's 23 a different insurance company involved, 24 if the data only resides with that</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. When you evaluated the 2 studies that you looked at, did you 3 evaluate that concept? 4 A. Whether they changed 5 insurance companies? 6 Q. Right. Per country, the -- 7 how often they change -- they change 8 insurances and, therefore, you would have 9 loss of follow-up due to that issue? 10 A. I didn't track in particular 11 if that was the reason. 12 But just that I think in 13 these studies, which were relatively 14 short-term studies, I don't think the 15 authors of the studies, for the most 16 part, articulated that there was -- that 17 that was a problem. 18 So I -- 19 Q. Do you know -- 20 A. I'm sorry. 21 I just didn't see that 22 reported as a problem by the authors of 23 the studies. 24 Q. Do you know which countries</p>
<p style="text-align: right;">Page 47</p> <p>1 particular source, then, sure, it's a 2 shortcoming if you can't keep following 3 people. 4 Q. And that also happens in 5 other -- other -- not just the United 6 States, but other countries as well, 7 correct? 8 A. So I would only be guessing 9 about that. I mean, I don't -- I'm not 10 an, you know, expert in insurance 11 policies and so forth in other countries. 12 Q. Do you know if that happens 13 in Germany? 14 A. I have no idea. I think -- 15 I mean, I don't -- I don't know for sure 16 which -- you know, which countries have, 17 for example, you know, uniform government 18 insurance, which doesn't vary, you know, 19 versus having private insurance. 20 So if it became important, I 21 might be able to figure that out. But I 22 certainly don't hold, you know, myself as 23 an expert in insurance policies by 24 country.</p>	<p style="text-align: right;">Page 49</p> <p>1 are known for having the least -- the 2 least loss of follow-up due to change of 3 insurances? 4 A. No. 5 Q. When evaluating cancer, 6 that's an important issue to look at, in 7 terms of loss of follow-up due to 8 insurance, correct? 9 A. Any -- any outcome would be. 10 Q. But outcomes that have 11 longer latency, that would be an 12 important issue to look at, correct? 13 A. I'm not sure what that 14 means. I'm sorry. 15 Q. The longer the latency, the 16 more there is an issue -- the longer the 17 latency of the outcome that you're 18 evaluating, the more there's an issue in 19 terms of loss of follow-up due to an 20 insurance switch? 21 A. Yeah. Sure. It could be. 22 I understand now. Thank you. 23 So, yeah, if you have an 24 exposure and an outcome that you're</p>

<p style="text-align: right;">Page 50</p> <p>1 tracking and there needs to be sufficient 2 latency, and if loss to follow-up occurs, 3 you know, within that latency time -- 4 within the latency that you believe that 5 you need in order to make the study have 6 the information, then, sure, it would 7 have an impact. 8 Q. And that sort of loss of 9 follow-up due to switching of insurances, 10 that would normally leave to Type II 11 bias, correct? 12 A. If -- well, type -- it's not 13 a bias. I mean, Type II refers to an 14 error, right. It's not a bias. 15 And there's an error that 16 can occur because you failed to 17 demonstrate the -- the risk that might be 18 there. But it's not a bias as much as it 19 is an error. 20 Q. Loss of follow-up due to 21 switching jobs and, therefore, switching 22 insurances, that would lead toward bias 23 toward the null, correct, more often than 24 not?</p>	<p style="text-align: right;">Page 52</p> <p>1 A. Well, so false positives 2 aren't a bias, right, they're an error, 3 right. So you wouldn't expect to get a 4 false positive from loss to follow-up, 5 right. That wouldn't be the reason. 6 The positive signal you got 7 would occur prior to the person leaving 8 the cohort. So if it's a false positive, 9 that's a completely different issue and, 10 I don't think, has anything to do with 11 switching, you know, per se. 12 Unless, you know, you're 13 switching in and out of one group that 14 has, you know, better and worse quality 15 data. But otherwise, I don't -- I don't 16 think that's -- that's not something you 17 really compare. 18 Q. Non-differential 19 misclassification generally leads toward 20 bias toward the null, correct? 21 A. That's the general belief, 22 yes. But it's not a guarantee. It's a 23 supposition. 24 Q. And one type of</p>
<p style="text-align: right;">Page 51</p> <p>1 A. You know, in theory, it 2 could. But the truth of it is you 3 wouldn't know. You know, it could work 4 either way. 5 Q. Have you looked at studies 6 that evaluated whether or not loss of 7 follow-up due to insurance issues more 8 likely leads to bias toward the null 9 versus false positive biases? 10 A. I don't -- I don't recall 11 ever seeing a study that made that 12 their -- you know, their topic. 13 But I may have seen 14 something, you know, years ago. 15 Q. Have you reviewed any 16 position papers that discuss that issue? 17 A. Not in recent times. I 18 don't know if I have in the past. But, 19 you know, definitely not recently. 20 Q. Do you have any reason to 21 believe that loss of follow-up due to 22 insurance switching would not more often 23 lead to bias toward the null versus false 24 positive bias?</p>	<p style="text-align: right;">Page 53</p> <p>1 non-differential misclassification could 2 be loss of follow-up due to switching 3 insurances; is that correct? 4 A. Well, I don't know. Only in 5 the sense that it could be. You know, 6 but the -- but, you know, when you're 7 talking about, you know, things that bias 8 towards the null and that have 9 non-differential, then it makes an 10 assumption that the reason for switching 11 is not informative, right. And so you 12 would need that information, too. 13 If there's an informative 14 reason for switching, then that might 15 work the other way. 16 Q. Loss of insurance due to 17 switching jobs generally leads to 18 non-differential misclassification that 19 leads towards bias toward the null, 20 correct? 21 A. No. And I -- if some of 22 these questions are meant to be 23 different, I'm not sure I'm hearing the 24 exact difference in them.</p>

<p style="text-align: right;">Page 54</p> <p>1 I think I've kind of covered 2 it in terms of the best answers I can 3 give to these topics so far. 4 But if I'm missing what's 5 different about that last question, I'm 6 happy to take another crack at it. 7 Q. The difference between the 8 last question versus the question I asked 9 before is the reason for switching 10 insurances. 11 So people are switching 12 jobs, that would tend to lead to 13 non-differential misclassification that 14 would lead toward bias -- 15 A. No, I wouldn't agree with 16 that. I mean, you need to know more. I 17 mean, why are they switching jobs? You 18 know, there might be a lot of information 19 on why they're switching jobs. 20 Maybe they're sick. Maybe 21 they're sick and they can't keep working 22 in the same job. Maybe they were fired 23 because they come to work drunk, you 24 know, and they get moved another place.</p>	<p style="text-align: right;">Page 56</p> <p>1 haven't -- I haven't done that. I mean, 2 I'm not aware. 3 I may have seen something 4 years ago. But I'm not aware of anything 5 recently that I have seen. 6 Q. So you would not have 7 considered that in your opinions that you 8 gave here today, correct? 9 ATTORNEY DAVIDSON: I'm 10 going to object. Like, I feel 11 like you're just asking and 12 answering the same questions over 13 and over. 14 ATTORNEY NIGH: They're not 15 the same questions. That's a 16 different question. 17 BY ATTORNEY NIGH: 18 Q. Doctor, you can answer. 19 A. Sure. 20 ATTORNEY NIGH: And that's 21 an inappropriate objection, by the 22 way. 23 BY ATTORNEY NIGH: 24 Q. You can answer, Doctor.</p>
<p style="text-align: right;">Page 55</p> <p>1 So when you switch jobs, 2 it's not a random event, usually, right. 3 There's a reason for it. And so that 4 information could have a big impact on, 5 you know, what happens to the study. 6 Q. You just talked about a lot 7 of maybes and this could happen. 8 But I was asking -- my 9 question was generally, as you look at 10 the range of ways that people switch jobs 11 in a whole, in a population, doesn't that 12 generally lead to non-differential 13 misclassification that leads towards bias 14 towards the null? 15 A. Yeah, I can't endorse that. 16 I don't -- I don't think I have enough 17 information to endorse that. 18 Q. Have you reviewed any 19 studies that -- that look at this issue 20 as to whether or not switching jobs and, 21 therefore, switching insurances would 22 tend to lead toward bias toward the null? 23 A. No. I think you asked that 24 also. And I still don't -- I mean, I</p>	<p style="text-align: right;">Page 57</p> <p>1 A. Sure. Thank you. 2 So, I mean, what it links to 3 is that -- what I said earlier that I 4 didn't see that the authors of the 5 studies, you know, detected that as a 6 particular concern in their studies. 7 You know, I looked for 8 what -- you know, including what the 9 authors of the studies found to be 10 concerns in the studies that we're 11 talking about. 12 So it's not that I didn't 13 consider it. I just didn't see that it 14 was an issue that was raised as important 15 enough to change these studies. 16 Q. Do you have any way of 17 knowing, in these various studies, which 18 studies that would have affected more, 19 that people would have switched 20 insurances and, therefore, had loss of 21 follow-up? 22 ATTORNEY DAVIDSON: I'm 23 going to object. The question 24 lacks foundation.</p>

<p style="text-align: right;">Page 58</p> <p>1 THE WITNESS: If it's 2 written in there, I have a way to 3 find out, which is for us to look 4 at the studies again. 5 But I don't recall, you 6 know, something off the top of my 7 head that would let me answer that 8 question. 9 BY ATTORNEY NIGH: 10 Q. But if you're looking at 11 each individual study versus a systematic 12 review of the studies, how would you do 13 the comparison? 14 A. Just trying to answer your 15 question. I mean, I wouldn't have 16 planned to do it in any case. I mean, 17 not to rank order that way. 18 I'm literally just 19 responding to a question that doesn't 20 really make a lot of sense to me. But 21 I'm just -- I'm just thinking -- since 22 you asked it, I'm just trying to answer 23 it. 24 Q. In your systematic review,</p>	<p style="text-align: right;">Page 60</p> <p>1 I mean, as I looked through 2 each article, I looked for sort of 3 strength and weaknesses. I don't know if 4 I saw a lot of others that would be 5 non-differential. 6 I know that the authors 7 sometimes talk about things that they're 8 hopeful for, you know, which is that 9 they're hoping that confounders might be 10 distributed similarly between groups. 11 But when I considered that, 12 I actually saw evidence to the contrary, 13 right. So when they would talk about, 14 you know, important confounders, they 15 often were not distributed the same 16 between, like, for example, the 17 contaminated user group and the 18 non-contaminated user group. So I saw 19 suppositions about things like that. 20 But it didn't seem like it 21 held up when you actually look at the 22 findings. 23 Q. Doctor, if users of both 24 contaminated valsartan and uncontaminated</p>
<p style="text-align: right;">Page 59</p> <p>1 did you evaluate which studies would have 2 been more likely to have 3 misclassification bias due to switching 4 of insurances versus which studies would 5 have been less likely to have that bias? 6 A. Yeah, I mean, my answer is 7 going to be the same over and over again 8 here. 9 Like, I didn't track that 10 they saw that as a problem. I have the 11 skill set to go back and look at the 12 specific question, if you believe that 13 there's something there for us to look at 14 that would be fruitful. 15 But I certainly didn't 16 memorize anything about these few studies 17 that would tell me how to rank order 18 them. 19 Q. What other non-differential 20 misclassification biases did you 21 consider? 22 A. I'd have to look back and 23 look at each article to think -- to think 24 that through.</p>	<p style="text-align: right;">Page 61</p> <p>1 valsartan were -- were included in both 2 the test and control groups, that would 3 also lead toward bias toward the null, 4 correct? 5 A. So let me just correct you. 6 I know Dr. Sawyer referred 7 to things as a test group. There were no 8 test groups in these studies, right. A 9 test group is a group that's experimented 10 upon. And none of these were 11 experiments. 12 But if you're talking 13 about -- and then can you say the rest of 14 it again? Because I'm sort of stuck on 15 the -- like, the kind of misuse of the 16 terminology. 17 Q. No problem. 18 Doctor, if studies evaluated 19 users that were both exposed and 20 unexposed and put them into both groups 21 in the -- in the analysis, that would 22 lead toward bias toward the null, 23 correct? 24 A. And to clarify, so you're</p>

<p style="text-align: right;">Page 62</p> <p>1 talking about, like, the same individual 2 was in both categories at different time 3 periods? 4 Q. No. The same individuals in 5 both categories, period. Not at 6 different time periods. 7 A. Oh, well, how could that 8 work? I mean, you can only take one -- 9 one medicine at a time, right, of the 10 same type? 11 So you're saying people 12 were, like, doubling up and taking 13 uncontaminated and contaminated valsartan 14 in the same time period? 15 A. Doctor, if a person took 16 exposed medication one month and the next 17 month they took unexposed medication, 18 that person would be -- was included in 19 both groups in the Gomm study and 20 Mansouri study, correct? 21 A. That's what I was saying. 22 That's how I was answering before when 23 you asked it. 24 Q. Right. And that -- that</p>	<p style="text-align: right;">Page 64</p> <p>1 phenomenon and show how it can -- I don't 2 think I've seen a study. 3 I mean, I'm generally 4 familiar with the concept and my own 5 understanding and my colleagues' 6 understandings generally about the topic. 7 I don't know if I've read an 8 article that -- that's about that. 9 Q. Have you -- in forming your 10 opinions in this case, did you consider 11 any studies that looked at systematic 12 reviews of papers published by authors 13 who had conflict of interest versus 14 papers that were published by authors who 15 did not have conflict of interest? 16 A. So I don't -- you know, I 17 don't recall, one by one, which, if any, 18 had reported, you know, potential or 19 actual conflicts of interest. 20 I read that at the time that 21 I looked at each study. But I can't -- 22 you know, I can't recall enough, you 23 know, sitting here without looking at 24 them to answer your exact question.</p>
<p style="text-align: right;">Page 63</p> <p>1 leading of including that same person in 2 both groups could -- could lead toward 3 bias toward the null, correct? 4 A. It could. 5 Q. Did you look at any analyses 6 where they excluded them from both 7 groups? 8 A. I think -- I'll have to look 9 at each study to remember. I think there 10 was at least a study -- one study that 11 did, like, a sensitivity analysis and 12 looked at people who were in different of 13 the groups of the type that you're 14 talking about. 15 But I think that the -- I 16 think that the overarching analyses for 17 these studies was basically people 18 divided into users versus non-users. 19 And I'm talking specifically 20 about NDMA-contaminated valsartan. 21 Q. Doctor, have you reviewed 22 any studies that show how conflict of 23 interest of authors can affect results? 24 A. So studies that examine that</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. Doctor, what is the 2 hierarchy of evidence? 3 A. Are we talking about 4 epidemiological evidence? 5 Q. Yes. 6 A. So in general terms, it 7 refers to different study designs that 8 have, you know, more prominence than 9 others. 10 Q. And what would be at the top 11 of the hierarchy of epidemiological 12 evidence? 13 A. So for primary studies, 14 clinical trials would. In some schemes, 15 then, there are also, you know, like, 16 pooling-type studies, so meta-analyses, 17 for example, can get ranked higher than 18 clinical trials if they're pooling -- 19 pooling those studies. 20 Q. After clinical trials and 21 meta-analyses, what would be the next 22 highest level in the hierarchy? 23 A. So then you get into 24 observational epidemiologic studies and</p>

<p style="text-align: right;">Page 66</p> <p>1 then cohort studies and then 2 case-controlled studies. 3 Q. So for observational 4 studies, that would include cohort and 5 case-controlled studies, correct? 6 A. That's correct. 7 Q. And cohort studies would be 8 higher in the hierarchy of evidence than 9 case-controlled studies? 10 A. For some people, including 11 myself. But they -- they occupy, like, a 12 similar band, if you will. 13 You know, they're sort of, 14 like, clustered together within -- you 15 know, within the hierarchy. 16 Q. Why would you include cohort 17 studies as higher than case-controlled 18 studies in the hierarchy of evidence? 19 A. They have advantages. And, 20 you know, the advantages that are 21 important to me are, you know, 22 ascertaining the exposure status prior to 23 the development of the outcome. 24 And so they -- they're able</p>	<p style="text-align: right;">Page 68</p> <p>1 A. There were three, if we just 2 count the peer-reviewed -- the 3 peer-reviewed publications. 4 Q. And the Pottegård study 5 didn't have any liver cancer cases in the 6 exposed or unexposed valsartan groups, 7 correct? 8 A. That is correct. 9 Q. So you don't believe that 10 was sufficiently powered to assess 11 whether or not NDMA caused liver cancer, 12 right? 13 A. It's not just an issue of 14 power. You know, they had a short -- a 15 short follow-on, you know, period. 16 I mean, it's -- you know, 17 when people -- I think people misuse the 18 term not having enough power to find 19 something. Because, certainly, small 20 studies can find things. And it's not 21 impossible to find liver cancer even in a 22 smaller study. 23 But, you know, the smaller 24 size and short duration of follow-up</p>
<p style="text-align: right;">Page 67</p> <p>1 to eliminate one very important bias, 2 which is recall bias, which 3 case-controlled studies are susceptible 4 to. 5 Q. And recall bias can lead 6 towards -- 7 (Reporter clarification.) 8 BY ATTORNEY NIGH: 9 Q. -- a Type I error? 10 A. Yeah. So finding a signal 11 that is reported that isn't -- isn't the 12 truth. That's right. 13 Q. Doctor, you're not aware of 14 any clinical trials that looked and 15 assessed NDMA and valsartan, correct? 16 A. I have not seen any. 17 Q. Without the clinical trials, 18 the next highest level of evidence in the 19 hierarchy of evidence would be cohort 20 observational studies, correct? 21 A. That's right. 22 Q. And there were multiple 23 cohort studies conducted of looking at 24 NDMA and valsartan, correct?</p>	<p style="text-align: right;">Page 69</p> <p>1 would make it more challenging in order 2 to -- you know, to be able to confidently 3 exclude a risk from anything they were 4 looking at. 5 Q. Any time a study has zero 6 outcomes for both the exposed and 7 unexposed, that would call into question 8 the sufficiency of the power of the 9 study, correct? 10 A. No, it doesn't have to. It 11 may well be that there just aren't any of 12 that outcome in the population that's 13 being studied. 14 So it's not a guarantee that 15 it's -- that it's not sufficiently 16 powered. 17 Q. There's no way to perform a 18 power calculation when there's zero 19 subjects in both an exposed and unexposed 20 for a particular outcome, correct? 21 A. It depends upon what you 22 mean. I mean, there's some people that 23 oversimplify the concept of a post hoc 24 power calculation and what data you need.</p>

<p style="text-align: right;">Page 70</p> <p>1 But you can certainly 2 provide an estimate. I mean, if you had 3 an estimate of what you thought the 4 prevalence of the disease was in one 5 group and what you expected it to be in 6 the other group, you could provide an 7 estimate of what a study of that size 8 would be -- you know, what the power 9 would be. 10 Q. In terms of trying to do 11 that sort of power calculation, you have 12 to come up with an estimate that's 13 outside of the study, correct? 14 A. It would be -- right. It 15 would be information that you -- that you 16 already know or believe to be true. 17 And, again, you're talking 18 about a post hoc calculation, coming in 19 after the fact and doing the math. 20 Q. Doctor, it would be 21 unethical to knowingly give people 22 valsartan contaminated with NDMA in a 23 clinical trial, correct? 24 A. I would say likely so.</p>	<p style="text-align: right;">Page 72</p> <p>1 to me, comes from clinicians, for 2 example. 3 And these were not clinician 4 diagnoses, per se. These were -- these 5 were based on codes that were reported in 6 an administrative database. 7 Q. In order to report an ICD9 8 rescue type code, there would need to be 9 some basis that liver cancer was 10 detected, correct? 11 A. Hopefully. I mean, 12 although, you know, it's not a guarantee, 13 right. 14 And the reason I just say 15 that is, is that, you know -- and I don't 16 know who -- you know, who produced the 17 information in these studies to choose 18 the ICD9 or ICD10 codes. 19 But, you know, sometimes it 20 could be as simple as, you know, a 21 trained coder looking for the words 22 "liver cancer." And, you know, I've seen 23 examples, even in my own clinic, where 24 you put, like, rule-out, you know,</p>
<p style="text-align: right;">Page 71</p> <p>1 It depends, though, right. 2 What's unethical -- because -- I mean, 3 I -- I'm trying to anticipate, like, what 4 the reason is for your question, right. 5 So if an investigator 6 believed that the NDMA in the valsartan 7 was sufficient to raise the risk for 8 cancer and you were trying to study 9 whether or not, you know, people 10 developed cancer, that would clearly be 11 unethical. 12 Q. Doctor, the valsartan 13 epidemiological studies that you've 14 reviewed, they measured the outcome in 15 terms of diagnosis of liver cancer, 16 correct? 17 A. That's right. 18 Q. Okay. 19 A. Well, I mean, diagnosis 20 might be generous. It's the reporting in 21 administrative database. 22 I mean, to me -- but I get 23 your point. I am not trying to quibble. 24 But I just mean, you know, a diagnosis,</p>	<p style="text-align: right;">Page 73</p> <p>1 something and somebody picks up the thing 2 you're trying to rule out as the -- as 3 the thing, right. 4 So it's just not a 5 guarantee. But you hope that, on 6 average, that it does reflect, you know, 7 some truth about somebody -- somebody 8 somewhere in the clinical environment 9 having made that diagnosis. 10 Q. What you just described, 11 the -- somebody picking up rule-out, you 12 know, to that degree, that's a sort of 13 bias or error that would generally lead 14 toward non-differential misclassification 15 bias, correct? 16 A. I don't know. I mean, it 17 depends. But it -- but it certainly 18 could. 19 Q. Do you have any reason to 20 believe that that sort of error would 21 occur more often in a group of exposed 22 individuals compared to unexposed in a 23 cohort study? 24 A. Well, I don't know how many</p>

<p style="text-align: right;">Page 74</p> <p>1 different programs there are, for 2 example. Like, you know, some of these 3 are national databases. And so errors, 4 if there are errors, you know, could be 5 confined to a particular, you know, 6 center or particular region. 7 And so, you know, you could 8 get quite a distortion from errors that 9 aren't necessarily, you know, 10 system-wide, you know, meaning across, 11 you know, the entire country, like the 12 whole country of Germany, for example. 13 So, you know, I mean, if 14 there's errors that have something to do 15 with who is doing the coding or where 16 the -- the patients are that are 17 receiving the codes, you know, there 18 could be, you know, differential or 19 non-differential bias. 20 Q. Do you have any reason to 21 believe that that sort of error would 22 have occurred more often with the exposed 23 group compared to the unexposed group? 24 A. I mean, not based on these</p>	<p style="text-align: right;">Page 76</p> <p>1 validity of the diagnoses that they 2 thought they were recording. 3 But, I guess, you know, what 4 you're suggesting is a different study, 5 which none of these authors articulated, 6 which would be -- in order to find what 7 you're talking about, you know, you'd 8 have to, for example, you know, do a scan 9 or, you know, do whatever diagnostic 10 testing is required to detect 11 not-yet-diagnosed cancer. 12 So none of those described a 13 methodology like that. They are passive 14 recipients of whatever the coders, you 15 know, put into the administrative active 16 database. 17 Q. Right. There are other 18 diseases and outcomes where they attempt 19 to do that sort of study, where they -- 20 even on asymptomatic patients that may 21 have some sort of outcome that they're 22 assessing, by drawing blood or doing 23 scans, correct? 24 A. Oh, yeah. There's all sorts</p>
<p style="text-align: right;">Page 75</p> <p>1 studies. There's no information provided 2 within the studies that could -- could 3 inform that. 4 Q. The NDMA epidemiological 5 studies also measured the diagnosis of 6 liver cancer, or attempted to, correct? 7 A. Correct. They attempted to. 8 Q. And the NDMA occupational 9 study of Hidajat measured, as the 10 outcome, death due to liver cancer, or 11 attempted to, correct? 12 A. That's correct. 13 Q. Okay. In none of those 14 valsartan or NDMA epidemiological studies 15 did they attempt to assess whether 16 undiagnosed patients actually had cancer 17 but just were not diagnosed yet, correct? 18 A. So I think I understand. 19 I mean, at a -- at a high 20 level they didn't do any validation, 21 right. They didn't do any further 22 inquiry into any medical record or any 23 other source, right. They had no other 24 information about the accuracy or the</p>	<p style="text-align: right;">Page 77</p> <p>1 of studies where you can -- you can look 2 for not-yet-clinically reported, you 3 know, diagnoses. There's screening 4 tests, for example. 5 Q. For example, when assessing 6 what percentage of the population may 7 have celiac disease, they drew blood of 8 all patients, even those who were 9 asymptomatic, to assess what percentage 10 of the population has celiac disease, 11 correct? 12 A. I believe you. I don't know 13 the study you're referring to. But I 14 believe you. 15 Q. Okay. But that didn't occur 16 here with NDMA and valsartan for the NDMA 17 epidemiological studies, correct? 18 A. There was no -- there was no 19 attempt, in any of these studies, to link 20 any person-level clinical information 21 to -- you know, to the study database. 22 Q. Doctor, when you were 23 assessing the ranitidine studies, many of 24 those studies had active comparator</p>

20 (Pages 74 - 77)

<p style="text-align: right;">Page 78</p> <p>1 designs, correct?</p> <p>2 A. They did.</p> <p>3 Q. Do you pronounce that as</p> <p>4 comparator or comparator?</p> <p>5 A. I would say comparator. But</p> <p>6 I'm not sure I'm right. But that's --</p> <p>7 that's the way I would say it.</p> <p>8 Q. Okay. In looking at the</p> <p>9 active comparator studies, it would be</p> <p>10 important -- or what -- sorry. Strike</p> <p>11 that.</p> <p>12 What's the purpose of an</p> <p>13 active comparator in design?</p> <p>14 A. It's -- it's a very</p> <p>15 important, you know, issue, because --</p> <p>16 particularly for medications that treat</p> <p>17 symptoms, you know, for example.</p> <p>18 And if those symptoms are</p> <p>19 indicative of a disease that's in the</p> <p>20 causal pathway, right, to the outcome</p> <p>21 that you're looking at, then one of the</p> <p>22 ways to try to account for the risk of</p> <p>23 developing a disease would be to look at</p> <p>24 people who are on a similar medicine,</p>	<p style="text-align: right;">Page 80</p> <p>1 ranitidine studies that had an active</p> <p>2 comparator compared ranitidine with</p> <p>3 famotidine, correct?</p> <p>4 A. They had -- yeah.</p> <p>5 Famotidine is one. And then some of them</p> <p>6 also had proton pump -- proton pump</p> <p>7 inhibitors as well.</p> <p>8 Q. Did you assess whether or</p> <p>9 not the users of famotidine were a more</p> <p>10 diseased population than users of</p> <p>11 ranitidine?</p> <p>12 A. Whether they were more</p> <p>13 diseased?</p> <p>14 Q. Yes.</p> <p>15 A. In what way?</p> <p>16 Q. In many ways.</p> <p>17 Did you assess that in any</p> <p>18 way?</p> <p>19 A. I may have at the time I was</p> <p>20 reading them. But I think that the main</p> <p>21 issue is just that they -- you know, that</p> <p>22 they're indications -- I mean, the</p> <p>23 assumptions the authors made, on average,</p> <p>24 is that the indications for the drugs,</p>
<p style="text-align: right;">Page 79</p> <p>1 which would treat the same symptoms which</p> <p>2 would have something to do with the risk</p> <p>3 of the disease you're studying.</p> <p>4 And I can be specific if it</p> <p>5 helps because -- or maybe. Or not. I'll</p> <p>6 just wait for the question.</p> <p>7 Q. Well, when comparing an</p> <p>8 active comparator, it would be important</p> <p>9 that one of the -- that the active</p> <p>10 comparator would have a similar disease</p> <p>11 profile compared to the drug that you're</p> <p>12 testing, correct?</p> <p>13 A. You would hope so.</p> <p>14 And, again, you're not</p> <p>15 testing, it, right. You're not testing</p> <p>16 the drug.</p> <p>17 Q. Measuring?</p> <p>18 A. Sure. No, I'm sorry, I'm</p> <p>19 just -- I'm just listening to the</p> <p>20 questions, and I'm just trying to -- I'm</p> <p>21 just trying to make sure I'm answering</p> <p>22 what you're asking.</p> <p>23 Q. I understand. I understand.</p> <p>24 So in -- Doctor, most of the</p>	<p style="text-align: right;">Page 81</p> <p>1 you know, wouldn't differ, you know,</p> <p>2 between ranitidine and famotidine --</p> <p>3 famotidine and also the proton pump</p> <p>4 inhibitors.</p> <p>5 So, I mean, that was an</p> <p>6 assumption, I think, rather than a fact.</p> <p>7 Q. Did you assess any of the</p> <p>8 studies to see that famotidine users were</p> <p>9 more likely to use alcohol than</p> <p>10 ranitidine users?</p> <p>11 A. If I saw it at the time, I</p> <p>12 don't recall it today.</p> <p>13 Q. Do you recall if the studies</p> <p>14 demonstrated that famotidine users were</p> <p>15 more likely to have serious liver</p> <p>16 diseases than ranitidine users?</p> <p>17 A. I don't recall that. But</p> <p>18 I'm happy to look at the -- at the</p> <p>19 studies again.</p> <p>20 Q. And those sorts of outcomes</p> <p>21 could affect the results of those</p> <p>22 studies, correct?</p> <p>23 A. So if -- if one of the</p> <p>24 groups had more sort of already existent</p>

<p style="text-align: right;">Page 82</p> <p>1 disease, it could affect the outcomes. 2 Q. Did you do that same 3 assessment for PPI users versus 4 ranitidine users? 5 A. Well, I didn't separate it. 6 I just looked to see what the active 7 comparators were in the studies and the 8 rationale for it. 9 Q. Doctor, when doing a 10 systematic review, it's important not to 11 cherry-pick the results that favor one 12 conclusion and ignore the results that go 13 against that conclusion, correct? 14 A. Yes. I like that concept. 15 Q. Doctor, nearly all 16 observational studies have limitations, 17 correct? 18 A. Yeah. Every study -- every 19 study has limitations. 20 Q. And in nearly every study, 21 the study authors in observational 22 studies nearly always point out 23 limitations in their studies, correct? 24 A. Most of them do. And they</p>	<p style="text-align: right;">Page 84</p> <p>1 deposition or at trial, correct? 2 A. I don't know the number. 3 But, I mean, if you have some testimony 4 list and that's the count you made, I 5 don't disagree with you. 6 Q. Okay. Does that sound 7 accurate or in the ballpark? 8 A. Yeah, I would have estimated 9 a little lower than that. But, I mean, 10 you know, not -- not tremendously lower. 11 Q. Okay. And in those -- in 12 the last four years, have you ever 13 testified on behalf of plaintiffs? 14 A. Yes. 15 Q. Okay. And in which of those 16 cases did you testify on behalf of 17 plaintiffs? 18 A. I'd have to look at the -- 19 at the list, which I don't have in front 20 of me. 21 But, like, there was, like, 22 one -- one that I can think of was a 23 woman who had indoor mold and dampness in 24 her home that led to worsening of her</p>
<p style="text-align: right;">Page 83</p> <p>1 post that -- they point out some, but not 2 always all. 3 ATTORNEY NIGH: We've been 4 going for about an hour. Do you 5 want to take a break at this 6 point? 7 THE WITNESS: That would be 8 great. Just, like, five minutes 9 or something just to refill the 10 coffee. 11 VIDEO TECHNICIAN: Off the 12 record, 12:11. 13 - - - 14 (Whereupon, a brief recess 15 was taken.) 16 - - - 17 VIDEO TECHNICIAN: We are 18 back on the record at 12:41 p.m. 19 BY ATTORNEY NIGH: 20 Q. Doctor, I want to talk about 21 your past testimony, okay? 22 A. Sure thing. 23 Q. In the past four years, you 24 have testified over 60 times either in</p>	<p style="text-align: right;">Page 85</p> <p>1 lung disease. 2 And there was at least one 3 other case. I don't know if I can recall 4 which one it was. 5 But I think there's -- I 6 think there's at least two in terms of 7 testimony for the last four years. 8 Q. Do you have your expert 9 report in front of you? 10 A. I do. 11 Q. But you don't have your 12 prior testimony? 13 A. That's right. Yeah, I mean, 14 I just -- I have, like, a printout, like, 15 a hard copy of my report. 16 Q. No problem. 17 Okay. Do you recall what 18 the second case was where you testified 19 on behalf of plaintiffs? 20 A. Oh, no. I mean, I'm trying 21 to say, like, I would need to look at the 22 list, you know, to see. 23 Q. Approximately -- or, I'm 24 sorry. Strike that.</p>

<p style="text-align: right;">Page 86</p> <p>1 When did you start doing 2 consulting work for litigation? 3 A. At least -- at least 20 4 years ago, I think, was, like, the first 5 case. 6 Q. Okay. And what percentage 7 of your work would you -- in terms of 8 litigation consulting in the past ten 9 years would you say was on behalf of 10 plaintiffs versus on behalf of 11 defendants? 12 A. It's hard to -- so in 13 aggregate, it's hard -- the math is hard. 14 But by category, I'd say 15 that, like, where it's medical 16 malpractice cases, it's been about half 17 and half. You know, there -- there -- 18 for certain topics, like indoor dampness 19 and mold, I'd say it's probably also 20 50/50, maybe with a slight -- maybe 21 slightly more for plaintiffs. 22 For, you know, separate 23 issues -- like you'll see talc-related 24 cases on there, it's always for</p>	<p style="text-align: right;">Page 88</p> <p>1 think back before ten years ago, 2 necessarily. 3 But for the last ten years, 4 I can't think of a case where I've 5 testified for the plaintiffs. 6 Q. Approximately how much money 7 have you earned in the past four years 8 for litigation consulting work? 9 A. So I'd say it kind of varies 10 year to year. I'm just going to try to 11 do it roughly. 12 It's not the same every 13 year. But I would say in a typical year 14 between 300 and 5 or \$600,000. 15 Q. Which pharmaceutical 16 manufacturers or manufacturers of 17 substances have you testified on behalf 18 of? 19 A. So I don't -- like, I don't 20 know about pharmaceutical. Like, maybe 21 none, with the exception of Johnson & 22 Johnson. Although, like, it's not in the 23 role of what their pharmaceutical are, 24 right, because we're talking about talc</p>
<p style="text-align: right;">Page 87</p> <p>1 defendants. 2 So it depends upon the -- 3 you know, the topic and what the 4 specifics of the case are. 5 Q. So in terms of -- have you 6 ever been an expert in medical device 7 cases? 8 A. I don't think so. You mean, 9 where there's like -- yeah, I don't -- I 10 don't think so. 11 Q. Like a hip or bladder, 12 implant or those sorts of things? 13 A. No, I don't -- I don't think 14 I've come across anything like that. 15 Q. So you spoke about talc. 16 In terms of cases that 17 involved manufacturers of substance, 18 whether it be, you know, drug 19 manufacturers or other substances, how 20 often do you testify on behalf of 21 plaintiffs versus on behalf of 22 defendants? 23 A. If it's manufacturers, I'd 24 say -- and you mentioned -- like, I can't</p>	<p style="text-align: right;">Page 89</p> <p>1 in those cases. 2 So, I mean, if you took 3 Johnson & Johnson, obviously they're -- 4 they're a pharmaceutical company also. 5 But I -- I haven't testified, you know, 6 on my matter relating to a 7 pharmaceutical. 8 And I don't think that 9 there's anything -- anything on that list 10 that you would have that's about a 11 pharmaceutical, you know, issue. 12 Q. What about in terms of toxic 13 substances, which companies have you 14 testified on behalf of in terms of toxic 15 substances? 16 A. I think -- I mean, the best 17 way to do it is to kind of read through 18 that list that you have, because 19 that's -- that's a list of testimony. 20 So I won't do a complete 21 job, you know, just from memory. 22 But, like, Colgate, 23 Palmolive, for example, Avon. I think, 24 like, a couple of -- did you say</p>

<p style="text-align: right;">Page 90</p> <p>1 manufacturers? Is that what you said?</p> <p>2 Q. Companies or manufacturers.</p> <p>3 A. Okay. Yeah. There's been a</p> <p>4 couple of, like, talc suppliers that I've</p> <p>5 been, like, co-retained some certain of</p> <p>6 those cases, like IMI Fabi, Incorporated.</p> <p>7 And there was another one some years ago</p> <p>8 that went bankrupt.</p> <p>9 But whatever -- whatever is</p> <p>10 on the list that we provided is accurate.</p> <p>11 So the ones I'm not saying out loud are,</p> <p>12 you know, still true if they're on that</p> <p>13 list.</p> <p>14 Q. I understand. I only have a</p> <p>15 list for four years. So I'm just asking</p> <p>16 you just, in your history of testifying,</p> <p>17 which companies.</p> <p>18 A. Yeah. Well, it's the ones</p> <p>19 that are on that list. And off the top</p> <p>20 of my head, I can't think of ones that</p> <p>21 aren't on that list.</p> <p>22 Q. Okay. So in the -- prior to</p> <p>23 the last four years, you can't think of</p> <p>24 any companies or manufacturers that you</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. What is a potential</p> <p>2 confounding factor?</p> <p>3 A. It's the same thing.</p> <p>4 Although potential would have to do with</p> <p>5 the -- like, the investigator or the</p> <p>6 scientist, you know, based on what their</p> <p>7 knowledge is or their belief.</p> <p>8 So something that's a</p> <p>9 potential might be one that hasn't been</p> <p>10 shown but might be suspected to be a</p> <p>11 confounder.</p> <p>12 Q. Nearly all observational</p> <p>13 studies have potential confounding</p> <p>14 factors that are not able to be addressed</p> <p>15 in the study results, correct?</p> <p>16 A. That's right.</p> <p>17 Q. And just because some</p> <p>18 potential confounding factors are not</p> <p>19 ruled out, this does not necessarily make</p> <p>20 the study findings unreliable, correct?</p> <p>21 A. Not just because some. I</p> <p>22 mean, there's -- there's a hierarchy in</p> <p>23 some ways, you know, some are more</p> <p>24 important than others.</p>
<p style="text-align: right;">Page 91</p> <p>1 testified on behalf of?</p> <p>2 A. I can't. I mean, it doesn't</p> <p>3 mean there aren't any. But I'm not -- I</p> <p>4 can't think of any that wouldn't be on</p> <p>5 that list from the last four years.</p> <p>6 Q. Okay. Doctor, what is a</p> <p>7 confounding factor?</p> <p>8 A. As a term in epidemiology,</p> <p>9 it sometimes is -- and that's what we're</p> <p>10 talking about, right, epidemiology?</p> <p>11 Q. Yeah. What is a confounding</p> <p>12 factor in epidemiology?</p> <p>13 A. Thank you. No, I'm sorry.</p> <p>14 Because I know some people use words in</p> <p>15 English that, you know, mean something</p> <p>16 else --</p> <p>17 Q. No problem.</p> <p>18 A. -- from my field.</p> <p>19 So, like, a confounder or a</p> <p>20 confounding factor, it's, in -- in some</p> <p>21 schemes is considered a bias. And it's a</p> <p>22 factor that distorts the relationship</p> <p>23 between the two -- the true exposure and</p> <p>24 the outcome that you're studying.</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. How would you describe that</p> <p>2 hierarchy of which are more important</p> <p>3 than others?</p> <p>4 A. Oh. So, like, an example</p> <p>5 would be -- it may be in my report.</p> <p>6 But if you look at -- you</p> <p>7 know, if you look back -- back years ago,</p> <p>8 a lot of people who drank coffee also</p> <p>9 smoked cigarettes, right. So if you did</p> <p>10 a study of coffee drinkers and looked at</p> <p>11 lung cancer incidence, you would almost</p> <p>12 certainly find that coffee drinkers have</p> <p>13 a higher incidence of lung cancer.</p> <p>14 But, you know, we know</p> <p>15 pretty confidently that coffee doesn't</p> <p>16 cause lung cancer. And we know pretty</p> <p>17 confidently that tobacco smoke does. And</p> <p>18 so if your study didn't account for</p> <p>19 tobacco, that would be an example of an</p> <p>20 important confounder, you know, if you</p> <p>21 missed that, since that's the true cause</p> <p>22 of the outcome you're looking at.</p> <p>23 Q. And, generally, a</p> <p>24 confounding factor would be -- in the</p>

<p style="text-align: right;">Page 94</p> <p>1 example you gave, would be people who 2 drank coffee would more often smoke than 3 people who did not drink coffee, correct? 4 A. In that example, that's 5 right. 6 Q. And, generally speaking, 7 when looking -- when looking at 8 confounding factors, that would -- 9 generally would be what is needed, that 10 the one group more often has exposure to 11 something than the other group, correct? 12 A. In order for it to function 13 that way, that's right. There would be 14 more of that actual cause in one group 15 than another. 16 Q. For any of the valsartan 17 studies that you analyzed, did you find 18 any confirmed confounding factors? 19 A. So "confirmed" meaning that 20 they affirmatively looked at known or 21 suspected confounders that did influence 22 the results? 23 A. Yes. 24 Q. Well, they don't break it</p>	<p style="text-align: right;">Page 96</p> <p>1 like, a hazard ratio, after adjustment, 2 is a different value, then you know that 3 the -- you know, when you compare it to 4 the unadjusted result, the adjusted 5 result, if it's different, will have 6 accounted for those confounders. 7 But I didn't -- I didn't see 8 an analysis where they isolated a 9 particular confounder where we could say, 10 yeah, that one mattered or that one 11 didn't matter. 12 Q. For any of the NDMA dietary 13 studies that you analyzed, did you find 14 any confirmed confounding factors? 15 A. None specific in that way 16 that I'm describing, you know, where they 17 isolated a particular -- a particular 18 item. 19 Q. For the Hidajat study, did 20 you find any confirmed confounding 21 factors? 22 A. I don't know if I saw any. 23 I mean -- I mean, what I mostly noticed 24 was the -- you know, the absence of</p>
<p style="text-align: right;">Page 95</p> <p>1 down that way, right. I mean, I'd say in 2 general, right, that -- you know, for 3 example, like, some of the analyses were 4 adjusted for, say, you know, age and sex. 5 And, you know, older age is clearly a 6 risk factor for most cancers, you know, 7 just given the accumulation of time. 8 And so the -- you know, age 9 would be a potential confounder. And 10 then if you've accounted for it, then 11 you've done a good job of sort of 12 eliminating age as the -- as an actual 13 confounder in the study. 14 But the -- I didn't see, 15 like, enough detail in the reports to 16 say, you know, how much each and every 17 one of the studied confounders, whether 18 potential or not, influenced the results. 19 Q. Okay. So you did not find 20 any confirmed confounding factors for any 21 of the valsartan studies that you 22 analyzed, correct? 23 A. Not -- not individually. I 24 mean, to the extent that you see that,</p>	<p style="text-align: right;">Page 97</p> <p>1 consideration of some of the most 2 important confounding factors. 3 But, you know, again, I 4 didn't see, you know, like, the sort of 5 granular detail you'd need to say, okay 6 this -- this particular factor was 7 clearly a confounder because it was 8 studied, you know, in isolation or one by 9 one. 10 Q. And when you mention the 11 confounding factors in Hidajat, you mean 12 the potential confounding factors in 13 Hidajat? 14 A. What I was referring to? Is 15 that what you're asking? 16 Q. Yes. 17 A. Oh, yeah. So what they said 18 in the paper is that they -- you know, 19 they couldn't account for lifestyle 20 factors, for example. 21 So since it was a study 22 looking at liver cancer, among other 23 things. They had no information about 24 alcohol use. They didn't have tobacco</p>

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<p style="text-align: right;">Page 98</p> <p>1 use. So, I mean, as examples, those are 2 two important confounders. 3 And then, you know, even 4 though the preamble talks about multiple 5 carcinogens being in the environment of 6 the rubber workers, they only measured a 7 modest number of the exposures, right. 8 So that the other -- the other ones are 9 left hanging out there as potential 10 confounders, because they didn't measure 11 them and they didn't account for them. 12 Q. So for the alcohol and 13 smoking, those would be potential 14 confounding factors in the Hidajat study, 15 correct? 16 A. So not the way that I said 17 initially. I guess it's a matter of 18 semantics. And I just want to kind of 19 clarify it. And if I am not answering 20 it, please let me know and I'll try to -- 21 try to do, you know, better. 22 So when I was talking about 23 potential before, you know, an example 24 might -- there might be, like, in</p>	<p style="text-align: right;">Page 100</p> <p>1 So alcohol is a risk factor. 2 That risk factor -- because it can cause 3 or be on the causal pathway to the 4 outcome, which is liver cancer, and it 5 wasn't accounted for, it's still a 6 confounder. We just can't know what the 7 effect of it is in that study because 8 they didn't -- they didn't measure it. 9 Q. But there's nothing 10 suggesting that -- that people exposed 11 to -- in the fourth quartile of NDMA 12 would have drank more alcohol than people 13 exposed in the first quartile of the NDMA 14 in the Hidajat study, correct? 15 A. We can't know -- we can't 16 know one way or the other. 17 I mean, I would say that, 18 you know, just in general that, you know, 19 workers that have kind of the most or the 20 worst exposures often have clustering of 21 other unfavorable factors. 22 And so that might be, you 23 know, true in that study. But we 24 don't -- we don't have information to say</p>
<p style="text-align: right;">Page 99</p> <p>1 general, like, let's say somebody 2 wondered if eating chocolate bars was a 3 risk factor. They don't know it, but it 4 might be and maybe they have some good 5 reason for thinking about it. So it's a 6 potential confounder. It doesn't mean 7 it's going to be. That's how I meant 8 that particular issue. 9 So alcohol use clearly is a 10 confounding factor in a study of liver 11 cancer, you know, if you believe that 12 alcohol use is a risk factor for -- for 13 liver cancer. The -- so that's how I'm 14 using it. It's a actual confounding 15 factor. 16 But it can't be -- it can't 17 be studied in the Hidajat study because 18 they didn't -- they didn't measure it. 19 Q. When you use the terminology 20 that it is a con -- that alcohol is a 21 confounding factor in the study, you mean 22 that alcohol is a risk factor? 23 A. That's the way that one 24 functions. That's exactly right.</p>	<p style="text-align: right;">Page 101</p> <p>1 one way or the other. 2 Q. Do you have any reason to 3 believe that people who would work in the 4 vulcanizing department would drink more 5 alcohol than people who worked in other 6 departments in the factory? 7 A. Yeah. And not as a fact, 8 right. But in -- I've seen in multiple 9 worker studies where the people who are 10 in the worst environment -- and I would 11 assume the vulcanizing environment is not 12 very good, it must smell terrible and it 13 seems like it's a -- generally speaking, 14 from the way that the descriptions are in 15 that series of papers, you know, it 16 doesn't sound like the one people would 17 sort of work their way up to. You know, 18 it might be the -- kind of the most 19 menial or the most -- you know, for lack 20 of a better word, most disgusting, right. 21 So it's -- and then people 22 that are in those jobs often are of the 23 lowest socioeconomic status or have the 24 least power in the -- in the -- you know,</p>

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<p style="text-align: right;">Page 102</p> <p>1 in the company. And some habits go along 2 with that, you know, including smoking, 3 drinking and so forth. 4 Q. So is your belief that the 5 people who worked in the curing and 6 vulcanizing department were in the 7 nastiest part of the factory compared to 8 the other parts of the factory? 9 A. I don't know how to rank 10 order them. But it certainly -- it 11 certainly sounds like one that would be 12 an undesirable place to work. 13 Especially early on, like, 14 back before they lowered the -- the 15 levels of the different chemicals. 16 Q. Well, how would you -- did 17 you try to do any sort of analysis 18 comparing curing and vulcanizing compared 19 to the other departments in the factory? 20 A. No, I can't do that. 21 Q. Do you know whether or not 22 other departments in the factory where -- 23 the workers were exposed to more of other 24 carcinogens than in the curing --</p>	<p style="text-align: right;">Page 104</p> <p>1 looked for? 2 A. I wasn't trying to compare 3 the different departments. 4 I mean, really, my answer to 5 your question was just about what I know 6 about, you know, occupations and who 7 works in certain -- you know, certain 8 types of occupation and some unfavorable 9 factors that go along with it. 10 Q. Have you seen any sort of 11 suggestion that -- that shows that, 12 actually, other departments in the rubber 13 industry were exposed to more carcinogens 14 than the curing and vulcanizing 15 department? 16 A. I don't know anything about 17 that. 18 Q. Doctor, you mentioned that 19 workers in the rubber industry were 20 exposed to several carcinogens other than 21 NDMA. 22 Do you recall this? 23 A. I do. 24 Q. Which of those carcinogens</p>
<p style="text-align: right;">Page 103</p> <p>1 A. Than -- 2 Q. -- and vulcanizing 3 department? 4 A. Sorry. I didn't mean to cut 5 you off. 6 No, I don't think they 7 reported that. 8 Q. Do you know whether or not 9 other departments in the rubber industry 10 were exposed to more rubber dust and 11 rubber fumes than the vulcanizing -- 12 vulcanizing and curing department? 13 A. I don't recall seeing it 14 broken down that way. 15 Q. Do you know whether or not 16 other departments in the factory were 17 exposed to more of the carcinogen in more 18 than the curing and vulcanizing 19 department? 20 A. I don't know that. I don't 21 know if it's in the paper that we can 22 look at. 23 But I don't recall that. 24 Q. Is it something that you</p>	<p style="text-align: right;">Page 105</p> <p>1 do you believe are a risk factor for 2 liver cancer? 3 A. So I'd have to see the list 4 again. It's in the preamble. 5 I don't know off the top of 6 my head. Because I know they mentioned, 7 I think, benzene and heavy metals and a 8 few others. And I'm not aware that those 9 are risk factors for liver cancer, per 10 se. 11 But there may be others. 12 I'm not sure. 13 Q. Do you believe that workers 14 in the rubber industry have an overall 15 increased risk of liver cancer compared 16 to those who do not work in the rubber 17 industry? 18 A. I'd say maybe. I mean, 19 based on that -- that one study, you 20 know, they do calculate an elevated risk. 21 So I'd say, you know, if 22 that's all the information that we have, 23 that it's -- that it's possible. 24 You know, there was a</p>

<p style="text-align: right;">Page 106</p> <p>1 meta-analysis that preceded that that -- 2 you know, that looked at cancer risk 3 across rubber workers and multiple 4 studies, and it didn't show an elevation. 5 So I guess if we somehow 6 hierarchically decide this one study is 7 more important than the ones captured in 8 the meta-analysis, then maybe it's true. 9 Q. When you say the one study, 10 you're talking about the Hidajat study 11 that showed an increased risk of liver 12 cancer when exposed to NDMA? 13 A. That's right. That's the 14 one we're talking about. 15 Q. And when you talk about the 16 meta-analysis, I believe you're referring 17 to the Boniol study in 2017? 18 A. Yeah, '17 or '18. But, 19 yeah, the Boniol study. 20 Q. Do you recall, did you ever 21 do any sort of systematic review to see 22 if there were other meta-analyses or 23 other studies that showed that workers in 24 the rubber industry did not have an</p>	<p style="text-align: right;">Page 108</p> <p>1 communicate a lot of things. And in the 2 introduction, the authors chose to inform 3 the readers that there are many other 4 carcinogens in the environment. And they 5 also made it clear that they didn't 6 measure those. 7 And then in their 8 discussion, they also make clear that 9 they didn't -- they didn't create any 10 multi-pollutant models. So it's very 11 hard to know whether they isolated the 12 effect of anything that they're 13 reporting, including NDMA or rubber dust 14 or rubber fumes or the rest. 15 Q. And I believe when you say 16 "they" in your prior answer, you're 17 referring to the Hidajat study authors? 18 A. That's the study I believe 19 we're talking about, yeah. I'll try to 20 say otherwise, if I think we're talking 21 about a different study. 22 Q. I'm asking about carcinogens 23 in a rubber factory altogether. 24 There's not a -- there's not</p>
<p style="text-align: right;">Page 107</p> <p>1 increased risk of liver cancer? 2 A. I have not done any 3 systematic review on rubber workers. 4 I think that, you know, 5 my -- given my task here about NDMA, I 6 think I understand that the Hidajat study 7 that we're talking about is the one that, 8 you know, measured and discussed NDMA. 9 Q. When you're considering 10 whether or not exposure to all these 11 other carcinogens that people would have 12 in a rubber factory and whether or not 13 that might be a risk factor for liver 14 cancer, wouldn't you want to look at 15 studies that look at overall exposure of 16 workers in the rubber factory compared to 17 people who didn't work in the rubber 18 factory for liver cancer? 19 A. It could be helpful. But, 20 you know, the authors are doing their 21 job, you know, of trying to inform the 22 reader. 23 I mean, you know, the 24 purpose of an epidemiologic study is to</p>	<p style="text-align: right;">Page 109</p> <p>1 a demonstration that shows that overall 2 exposure to working in the rubber factory 3 leads to an increased risk of liver 4 cancer, correct? 5 A. Not according to the 6 meta-analysis that I saw. 7 And, you know, just -- and 8 to remind you that I said no, I've not 9 done a systematic review to find other 10 studies. 11 Q. And if this exposure to 12 carcinogens in a rubber factory were 13 actually leading to an increased risk in 14 liver cancer, wouldn't those sorts of 15 meta-analyses be the studies that you 16 would look at to see whether exposure to 17 those carcinogens was a risk factor for 18 liver cancer? 19 A. Sure. I mean, they would be 20 helpful. But they would also, then, 21 create the sense of a surprise that a 22 single study did find it. 23 So why would one study find 24 a risk when all the rest of them didn't?</p>

<p style="text-align: right;">Page 110</p> <p>1 Q. Well -- sorry. Go ahead. 2 A. No, I was going to say -- 3 that's it. I mean, that's a sufficient 4 answer. 5 Q. Hidajat was actually looking 6 at exposure to NDMA and whether or not 7 varying exposures to NDMA led to an 8 increased risk of liver cancer, correct? 9 A. So they included NDMA. 10 But my point is if you -- 11 you know, it wasn't because they didn't 12 find an elevated risk of liver cancer, 13 right. I mean, regardless of what the 14 substance was, if studies are looking at 15 the industry and they don't find it, 16 right, it's baked into it, whatever those 17 exposures are. 18 This -- the Hidajat study is 19 the one that made an attempt to relate 20 estimates of NDMA and, in a handful of 21 other exposures, you know, to the risk of 22 multiple cancers, including liver cancer. 23 Q. The meta-analyses, 24 they're -- they were -- like Boniol,</p>	<p style="text-align: right;">Page 112</p> <p>1 vulcanizing and curing department 2 previously, do you have any information 3 that would suggest that people exposed to 4 higher amounts of NDMA in the Hidajat 5 study were exposed to higher amounts of 6 other carcinogens compared to those who 7 were exposed to lower amounts of NDMA? 8 A. We can't know, which is an 9 incredibly important flaw in the study 10 and an incredibly important flaw if we're 11 trying to reach the judgment that NDMA is 12 the culprit, right. 13 Because if you look at the 14 way they said they were going to do their 15 analyses, they did separate models for 16 rubber dust, for example, and for rubber 17 fumes, as another example. And then one 18 other nitrosamine. 19 And by doing each one at a 20 time, they're doing single-pollutant 21 models that don't take into account the 22 correlation between each of those either 23 substances or circumstances. 24 And that's why, you know, at</p>
<p style="text-align: right;">Page 111</p> <p>1 they're looking at overall exposure to 2 working inside of a rubber industry 3 compared to those who don't work in the 4 rubber industry, correct? 5 A. That's right. 6 Q. They did not analyze whether 7 or not increased exposure to NDMA versus 8 lesser exposure to NDMA in the rubber 9 factory led to an increased risk of 10 cancer, correct? 11 A. That is correct. 12 Q. Only the Hidajat study looks 13 at increased risk -- increased exposure 14 to NDMA versus decreased risk of 15 exposure, and then the decreased exposure 16 of NDMA leads to an increased risk of 17 liver cancer, correct? 18 A. And I just -- just for me to 19 answer it as correct, I would have to 20 change "leads to" to "associated with." 21 But otherwise, I agree with 22 your -- your question. 23 Q. Other than the qualitative 24 description that you gave about the</p>	<p style="text-align: right;">Page 113</p> <p>1 the end, when they finish with, you know, 2 we didn't do multi-pollutant models and 3 they didn't even think that they had the 4 right statistical techniques to do it, it 5 leaves one wondering. 6 I mean, this could be as 7 simple as my example with coffee and lung 8 cancer, right. They found something 9 that's associated with an elevated risk, 10 but they haven't been able to isolate it 11 from the other -- other substances that 12 they looked at. 13 Q. How did Hidajat address 14 whether or not there were issues related 15 to multi-pollutant? 16 A. They mentioned that if -- at 17 the end, they said that you might want to 18 do it, or something, I'm paraphrasing 19 because I don't have it in front of me. 20 But they brought up the 21 issue that it might be done but that 22 they -- they themselves, I think, didn't 23 have the current statistical capacity to 24 do that sort of modeling.</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. Are you aware of whether or 2 not they did any sort of analyses related 3 to multi pollutants? 4 A. I think they studied 5 multiple pollutants. But I can't tell 6 from the study that they actually 7 accounted for multiple pollutants in any 8 one particular model. 9 So, for example, you know, 10 they looked at an elevated risk related 11 to rubber fumes, but I don't -- I can't 12 tell from the analysis that that accounts 13 for what the NDMA was and vice versa. 14 Q. Doctor, there were two 15 Hidajat studies, correct? 16 A. So there's -- there may be 17 more, but there's two I'm aware of. One 18 had to do with, I guess, application of 19 the job exposure matrix. But one was 20 sort of, like, the main results of the -- 21 you know, of the cancer risk. 22 If those -- if those are the 23 two you're thinking of, that's what I'm 24 thinking of.</p>	<p style="text-align: right;">Page 116</p> <p>1 have the paper in front of me -- but 2 where they talk about the models, for 3 example, for NDMA and, like, rubber dust 4 and rubber fumes. And they use the word 5 "or." They said they adjusted for things 6 and it said each of those "or," so not 7 "and." 8 So if they -- if they had 9 said that they adjusted for those -- 10 like, you know, one factor, another 11 factor "and" the third factor, that could 12 imply, you know, multi-pollutant models. 13 But they said "or," which 14 told me it was individual models all by 15 themselves. 16 Q. So you don't recall any 17 multi-pollutant analyses performed by 18 Hidajat? 19 A. Not of the types we're 20 talking about. 21 I mean, if they included 22 something else in their models that might 23 have been, you know, interesting. But 24 they certainly didn't include the -- you</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Did you look at the -- did 2 you analyze the study related to the job 3 exposure? 4 A. I did. And there's another 5 one that, like, pre -- precedes that, 6 that's also cited in Hidajat, which is 7 really the -- it's really the source of 8 the job exposure matrix. 9 So that study -- and I'd 10 have to look, but I'm blanking on the 11 first author, but it's not Hidajat for 12 that study. But I did -- I did read the 13 other Hidajat study, if it's the one 14 that -- if we're talking about the same 15 thing. 16 Q. Doctor, do you believe that 17 the Hidajat studies did not do any 18 analysis to determine multi-pollutant 19 issues? 20 A. Well, I can't tell that they 21 did. If you look at the -- if you look 22 at their method section, there's a 23 part -- and, again, I'm going to have to 24 visualize it in my mind, because I don't</p>	<p style="text-align: right;">Page 117</p> <p>1 know, the carcinogens that they mention 2 at the beginning that they didn't 3 measure. 4 And yeah -- I mean, I'll 5 leave it at that. 6 I mean, I saw that, you 7 know, ATSDR when they evaluated the 8 study, too, you know, also mentioned, you 9 know, the absence of multi-pollutant 10 models. 11 Q. And when you say "not of the 12 type" that -- that we mentioned or were 13 discussing, do you recall any 14 multi-pollutant analyses or any analyses 15 regarding whether or not multiple 16 pollutants were having an affect on their 17 outcomes? 18 A. I don't. But I'm just 19 wondering -- I mean, if you're looking at 20 something that shows one of the 21 pollutants that we're not as interested 22 in, maybe that's in one of the models. I 23 just don't recall. 24 But I'm talking about the</p>

30 (Pages 114 - 117)

<p style="text-align: right;">Page 118</p> <p>1 models that include the topics of 2 interest, you know, which are rubber dust 3 and rubber fumes and the different 4 nitrosamines. 5 And I know they had a 6 separate, like, category where they 7 summed together -- they had, like, a sum 8 score for nitrosamines more generally. 9 But that also is not 10 accounting for multiple pollutants. It's 11 just pooling -- you know, pooling a few 12 of a certain category into one analysis. 13 Q. So you don't recall any 14 analyses that looked at whether or not 15 multiple pollutants -- multiple 16 pollutants were having an affect on NDMA? 17 A. No, I don't. But, you know, 18 again, I don't have the papers in front 19 of me. And I wish I had a memory where I 20 could memorize every detail of every 21 paper. 22 But I've read it, and I just 23 don't recall it. 24 Q. Your opinion states that</p>	<p style="text-align: right;">Page 120</p> <p>1 just wants to show me what he's 2 talking about, I mean, I can react 3 to it. But I -- 4 BY ATTORNEY NIGH: 5 Q. It's not a memory test. But 6 I can ask these questions based on your 7 opinions. 8 So we don't have to show -- 9 I don't have to produce articles here in 10 your deposition. 11 A. I can locate it, though. 12 I'm just saying -- and I'll 13 just say this just to get it out there. 14 Like, if it's an important issue and we 15 need to solve it now, that's fine. 16 I mean, having said this and 17 if we go to trial, I'll be sure to look 18 at it and I'll answer your question more 19 deliberately if I don't have a chance to 20 do it today. 21 Q. But in your -- in forming 22 your opinions, you don't recall looking 23 at any sort of multi-pollutant analyses 24 or analyses that looked at whether other</p>
<p style="text-align: right;">Page 119</p> <p>1 there is no multi-pollutant analyses or 2 any analyses that shows whether or not 3 any other carcinogen had an effect on 4 NDMA, correct? 5 A. Well, or whether it modified 6 the effect of NDMA. I mean, that's in 7 particular what we're talking about, 8 whether it's NDMA in isolation, 9 accounting for the other pollutants of 10 interest, whether or not it alone is the 11 explanation for the elevated risk that's 12 been calculated. 13 And I'm just taking that 14 from their -- their methods section, from 15 their discussion where they talk about 16 it. And then also, you know, ATSDR sort 17 of reiterating that. 18 ATTORNEY DAVIDSON: Dr. 19 Diette, do you need the article to 20 talk about it? Because you are 21 entitled to look at it. This is 22 not a memory test. 23 THE WITNESS: I could do 24 that. Or, you know, if Mr. Nigh</p>	<p style="text-align: right;">Page 121</p> <p>1 carcinogens may have had an effect on the 2 NDMA analyses, correct? 3 A. Yeah. And we're talking 4 about in the Hidajat study that reports 5 the risks of different cancers, right? 6 That particular one? 7 Q. Yes. 8 A. Yeah. No, I don't -- I 9 don't recall that. 10 Q. Okay. Doctor, 11 hepatocellular tumors are capable of 12 being promoted in numerous ways, correct? 13 A. I imagine that is possible. 14 We're talking about human 15 beings here? 16 Q. In human beings, yes. 17 A. I imagine that is possible. 18 But that's not really my field. So I 19 don't -- you know, I don't know to the 20 extent to which that's true. 21 Q. Do you know whether some 22 carcinogens are capable of promoting 23 hepatocellular tumors? 24 A. I don't.</p>

<p style="text-align: right;">Page 122</p> <p>1 Q. And that's not something 2 that you sought out to research, correct? 3 A. No. It wouldn't have 4 informed my opinions for this case. 5 Q. Doctor, are you aware of a 6 recent body of literature concerning -- 7 regarding cancer that focuses on when and 8 how subclinical tumors progress to 9 clinical diagnoses? 10 A. Well, I don't know about -- 11 what you mean by "recent" literature. 12 I mean, there's -- you know, 13 one of the most fundamental, you know, 14 discoveries in the, you know, timespan of 15 my career has been, you know, looking at 16 colon polyps, for example, which are a 17 precursor lesion that progress, you know, 18 over a decade or more to become a 19 carcinoma. 20 So that's not recent, I 21 mean, but that's -- that's one of the 22 earliest that I'm aware of. 23 Q. Doctor, did you -- did you 24 look at any or research any literature</p>	<p style="text-align: right;">Page 124</p> <p>1 But it wasn't -- that topic 2 is not part of the body of literature 3 that was relevant for this -- you know, 4 for this case. 5 Q. So in forming your opinions, 6 you did not consider literature that 7 looked at when and how subclinical 8 hepatocellular carcinomas progressed to 9 clinical diagnoses? 10 A. I didn't. And it 11 wouldn't -- it wouldn't help me. 12 Q. Doctor, carcinogens that 13 have the ability to promote can also 14 promote liver tumors, correct? 15 A. I don't know what that 16 means. I mean, you're using "promote" 17 twice in the same question. 18 Q. Yes. 19 Carcinogens that have 20 promoter capabilities can also promote 21 liver tumors, correct? 22 A. Well, I don't know if that's 23 a generalization. I mean, it -- I mean, 24 it's such a broad question.</p>
<p style="text-align: right;">Page 123</p> <p>1 that discusses how hepatocellular 2 carcinomas go from being subclinical 3 tumors to progressing to clinical 4 diagnoses? 5 A. No, no. That's not my 6 expertise and not my field. 7 Q. Did you consider that 8 literature when making your opinions in 9 this case? 10 A. Well, I don't know what 11 literature you're referring to. 12 But as a concept, you know, 13 we're talking about epidemiologic 14 literature that as an endpoint of an 15 actually discovered tumor. 16 So, you know, that's what I 17 was focused on, which is what 18 epidemiologic studies look at, you know, 19 which is something that you can measure. 20 I guess if there were -- if 21 there were some different body of 22 literature looking at what we could call 23 subclinical, maybe pre-diagnosed, you 24 know, that might be interesting.</p>	<p style="text-align: right;">Page 125</p> <p>1 I mean, if you're saying, 2 for example, that something that's 3 capable of promoting growth of a skin 4 cancer could automatically do that for a 5 liver cancer, I certainly don't know that 6 to be true. 7 Q. My question is focusing on 8 liver tumors, not skin tumors. 9 So my question is, Doctor, 10 are you aware of whether or not 11 carcinogens that have promoter 12 capabilities can also promote liver 13 tumors in humans? 14 A. Yeah, but my answer is 15 exactly correct for the way you're asking 16 the question. 17 Because a carcinogen is 18 something that's capable of causing a 19 cancer in some part of the body under 20 certain circumstances, which doesn't mean 21 that it can do that in any part of the 22 body under any circumstances. 23 So if you're asking a 24 general question about a promoter, and</p>

<p style="text-align: right;">Page 126</p> <p>1 let's say we agree that it's a promoter, 2 because it's been found in some other 3 context, you know, that wouldn't -- that 4 wouldn't relate automatically to liver -- 5 liver tumors. 6 Q. Doctor, are you aware that 7 carcinogen -- are you aware of whether or 8 not carcinogens can promote liver tumors 9 in humans? 10 A. I think I answered that 11 before. I don't have that knowledge. 12 Q. And are you aware of whether 13 or not carcinogens can promote 14 hepatocellular tumors in humans? 15 A. Yeah, same -- same answer. 16 ATTORNEY DAVIDSON: 17 Objection. These questions are 18 overbroad. 19 ATTORNEY NIGH: Jessica, 20 please object to form. 21 BY ATTORNEY NIGH: 22 Q. Doctor, I'm sorry. I didn't 23 get your answer. 24 ATTORNEY DAVIDSON: This is,</p>	<p style="text-align: right;">Page 128</p> <p>1 answer is no. The short answer is no. 2 Q. Doctor, who is ZHP in this 3 case? 4 A. My understanding is that 5 they are a pharmaceutical manufacturer. 6 Q. And ZHP, that's Zhejiang 7 Huahai Pharmaceuticals? 8 A. Yes. 9 Q. What is ZHP's role in this 10 litigation? 11 A. I assume they're a 12 defendant. 13 Q. Do you know why ZHP is 14 involved in this litigation? 15 A. Not factually, no. 16 Q. Did you review any of 17 plaintiff's complaints in this 18 litigation? 19 A. The complaints? 20 Q. Yes. 21 A. I don't recall doing that. 22 I don't know if I received a complaint, 23 but I don't recall reviewing it. 24 Q. Doctor, what is an active</p>
<p style="text-align: right;">Page 127</p> <p>1 like, literally exactly how you 2 guys object. But we don't need to 3 argue. You and I get along. 4 Let's move on. 5 ATTORNEY NIGH: Okay. 6 THE WITNESS: I said it was 7 the same answer to -- like, to the 8 prior question. 9 BY ATTORNEY NIGH: 10 Q. Got it. 11 Doctor, there were multiple 12 dose response analyses -- sorry. Strike 13 that. 14 Doctor, there were dose 15 response analyses in the Gomm study and 16 the Mansouri study, correct? 17 A. That's correct. 18 Q. In terms of milligram dosage 19 per manufacturer of valsartan with NDMA 20 or NDEA, do you have any idea what the 21 market share was per manufacturer per 22 dosage of milligram of valsartan with 23 NDMA or NDEA was? 24 A. How would I know that? The</p>	<p style="text-align: right;">Page 129</p> <p>1 pharmaceutical ingredient? 2 A. I'll give you my answer, 3 which might not be the same as, you know, 4 a pharmacologist or, you know, a Ph.D., 5 you know, with a pharmacy background. 6 But, to me, it's the 7 component, you know, within a dosage of a 8 medication that has the activity that 9 you're -- you know, you're looking to use 10 for the effect. 11 Q. Doctor, do you know whether 12 ZHP is an active pharmaceutical 13 ingredient manufacturer? 14 A. I do not know that. 15 Q. What is a finished-dose 16 manufacturer? 17 A. I don't know that 18 terminology. 19 Q. Doctor, do you know which 20 finished-dose manufacturers manufacture 21 their valsartan using active 22 pharmaceutical ingredients manufactured 23 by ZHP? 24 A. I can't answer it because I</p>

<p style="text-align: right;">Page 130</p> <p>1 don't know the -- I don't know what that 2 first term in that question means. 3 Q. Doctor, have you ever heard 4 that finished-dose manufacturers utilize 5 active pharmaceutical ingredients in 6 manufacturing the pill? 7 A. I suppose if I knew what 8 that term meant I might have an answer. 9 But since I don't know what the term is, 10 I don't see how I could answer a question 11 like that. 12 Q. Do you know which 13 manufacturers utilized ZHP's active 14 pharmaceutical ingredients in their 15 pills? 16 A. I have no idea. 17 ATTORNEY DAVIDSON: 18 Objection. Asked and answered. 19 BY ATTORNEY NIGH: 20 Q. Doctor, did you compare the 21 levels of NDMA and NDEA in the valsartan 22 of those manufacturers who used active 23 pharmaceutical ingredients manufactured 24 by ZHP with the levels of NDMA or NDEA of</p>	<p style="text-align: right;">Page 132</p> <p>1 And I'm not asking you to 2 reword it, because I don't know what 3 you're talking about. 4 Q. Doctor, do you have any idea 5 of which manufacturers of valsartan had 6 higher levels of NDMA and NDEA in their 7 valsartan? 8 A. I have -- I have no 9 awareness one way or the other. 10 Q. Doctor, do you have any idea 11 as to the magnitude of how much higher 12 the levels of NDMA and NDEA were for some 13 manufacturers of valsartan compared to 14 other manufacturers of valsartan? 15 A. I don't know whether there 16 were differences and some were higher. 17 But I don't -- I don't have any basis to 18 answer that question. 19 Q. Would you have any basis to 20 answer whether or not some manufacturers 21 had hundreds of times higher amounts of 22 NDMA and NDEA in their products compared 23 to other manufacturers of valsartan? 24 A. Not sitting here now based</p>
<p style="text-align: right;">Page 131</p> <p>1 those manufacturers who did not use 2 active pharmaceutical ingredients 3 manufactured by ZHP? 4 A. And the first verb was what? 5 Did I analyze that? 6 Q. Yes. 7 A. I don't have that capacity. 8 I mean, if there was a report you wanted 9 to show me, I could maybe read it. But I 10 don't have the capacity to do an analysis 11 of that. 12 Q. Did you compare those levels 13 in any way? 14 A. No. I'm not even sure what 15 we're talking about. 16 Q. Do you have any idea of how 17 the levels of NDMA and NDEA in the 18 valsartan manufactured using the active 19 pharmaceutical ingredients manufactured 20 by ZHP compare with the levels of NDMA 21 and NDEA of manufacturers of other 22 valsartan pills? 23 A. I don't have any capacity to 24 answer that question.</p>	<p style="text-align: right;">Page 133</p> <p>1 on what I know. 2 Q. Doctor, do you know whether 3 manufacturers of valsartan that contain 4 much higher levels of NDMA and NDEA had a 5 higher market share of lower valsartan 6 dosages compared to the manufacturers of 7 valsartan that contained much lower 8 levels of NDMA and NDEA? 9 A. Absolutely not. I don't 10 even know how to begin to answer a 11 question like that. 12 Q. Wouldn't -- wouldn't that 13 information be important in assessing 14 dose response sought out by Gomm and 15 Mansouri when they looked at milligrams 16 of valsartan use in assessing dose 17 response? 18 A. Not a bit. I mean, it's -- 19 I'm -- I'm left with the publication that 20 they have presented through peer review, 21 and I can analyze the results of that 22 publication. 23 But if there's other 24 differences you're talking about, I think</p>

<p style="text-align: right;">Page 134</p> <p>1 that's for somebody else to ask and 2 potentially answer. 3 But I -- you know, the paper 4 as it is, is complete, at least for the 5 sake of me being able to analyze it. 6 Q. But, Doctor, if -- if the 7 manufacturers who had much higher levels 8 of NDMA and NDEA, had a much higher 9 market share of 40 milligrams, for 10 example, than the manufacturers of -- 11 that had lower levels, much lower levels 12 of NDMA and NDEA, wouldn't that affect 13 the dose response analysis? 14 ATTORNEY DAVIDSON: 15 Objection. Improper hypothetical. 16 THE WITNESS: I mean, 17 there's so much missing from that 18 for me. Like, I don't even know 19 what you're implying. Like, 20 whether you're implying that there 21 are some -- some of the pills in 22 this study -- or that the study 23 didn't capture certain pills from 24 other manufacturers.</p>	<p style="text-align: right;">Page 136</p> <p>1 A systematic review doesn't 2 include looking at all of the different 3 scientific issues, you know -- and, 4 particularly, I don't even know if these 5 are scientific issues. These sound like 6 product issues or something to do with, 7 you know, somebody who knows something 8 about different manufacturing processes 9 or who knows what. 10 But it's -- all of these 11 things pertain to something that's not in 12 my field. 13 Q. But dose response analyses 14 that were performed in Gomm and Mansouri, 15 they're looking at the amount dose of 16 valsartan not the amount of NDMA that 17 people ingested in those studies, 18 correct? 19 A. So they're starting with 20 that. But they made some assumptions 21 about what they believed that the NDMA 22 dose would be. 23 But they're -- but they 24 literally have, because this is -- I</p>
<p style="text-align: right;">Page 135</p> <p>1 I don't know if that's what 2 you're saying. I don't know if 3 you're saying within the study 4 there were different 5 manufacturers. 6 I have no idea. I mean, 7 literally, as an epidemiologist, 8 the only thing I can do is look at 9 the results as they're presented 10 by the investigators that have 11 been through the peer-review 12 process and interpret what they've 13 written. 14 BY ATTORNEY NIGH: 15 Q. But you're doing a 16 systematic review. 17 So you can actually 18 compare -- you can look at other 19 literature and other sources of 20 information when you compare results 21 within a single study, correct? 22 A. No. I mean, a systematic 23 review, as you describe it, is a review 24 of the actual other epidemiologic study.</p>	<p style="text-align: right;">Page 137</p> <p>1 mean, for better or worse, this is what 2 you're left with in a 3 pharmacoepidemiology study, right, is you 4 have dispensations of a product, and 5 that's their exposure information. Their 6 dispensations. So whatever is in those 7 dispensation is baked into it, right. 8 I didn't see that either 9 study did an analysis of individual pills 10 to see what's in it or not. They are, 11 you know, it's -- whether it's a weakness 12 or not, it's something that isn't 13 available in a pharmacoepidemiology study 14 where you just literally look at pharmacy 15 dispensations. 16 Q. Doctor, the Gomm and 17 Mansouri studies also looked at whether 18 or not using valsartan for three or more 19 years led to an increased risk comparing 20 exposure to unexposed, correct? 21 A. So Gomm three -- I mean, 22 you're combining the two, right, so it's 23 Gomm three and the Mansouri, you know, 24 more than three.</p>

35 (Pages 134 - 137)

<p style="text-align: right;">Page 138</p> <p>1 So it's correct, if you --</p> <p>2 if you phrase it that way.</p> <p>3 Q. Okay. And when they looked</p> <p>4 at three or more than three they found a</p> <p>5 higher increased risk compared to</p> <p>6 overall -- their overall analyses,</p> <p>7 correct?</p> <p>8 A. So in one of the studies</p> <p>9 there was a numerically higher hazard</p> <p>10 that was no longer statistically</p> <p>11 significant. So I think one could</p> <p>12 appropriately argue they found no risk</p> <p>13 with the longer duration.</p> <p>14 Q. Okay. You believe that just</p> <p>15 because it's not statistically</p> <p>16 significant that that can be argued that</p> <p>17 no risk was found?</p> <p>18 A. Yeah. I think -- you know,</p> <p>19 the thing is with a study is that, you</p> <p>20 know, hopefully, they're not just</p> <p>21 providing statistical significance for no</p> <p>22 reason whatsoever, right.</p> <p>23 I mean, the information</p> <p>24 about the 95 percent confidence intervals</p>	<p style="text-align: right;">Page 140</p> <p>1 A. No. No, that's incorrect.</p> <p>2 And I think you could wish</p> <p>3 for that to be true. But it would be</p> <p>4 chaos. It would be absolutely chaos if</p> <p>5 we just cherry-picked every single</p> <p>6 finding from every study that supported</p> <p>7 some idea that was pointing in one</p> <p>8 direction or another that didn't reach</p> <p>9 statistical significance. It would be</p> <p>10 chaos. How do you interpret that, then?</p> <p>11 Q. A non-statistically</p> <p>12 significant increased risk would still be</p> <p>13 an increased risk that could be due to</p> <p>14 chance, correct?</p> <p>15 A. Whether it's statistically</p> <p>16 significant or not, it can be due to</p> <p>17 chance, right; either one can be due to</p> <p>18 chance.</p> <p>19 But this -- that would be</p> <p>20 one that failed the significance testing,</p> <p>21 which is part of doing epidemiologic</p> <p>22 studies.</p> <p>23 Q. Doctor, you rely on</p> <p>24 non-statistically significant risk in</p>
<p style="text-align: right;">Page 139</p> <p>1 and the P value is there, right. It's</p> <p>2 required by most journals, and most</p> <p>3 people know how to interpret it.</p> <p>4 So conventionally if you</p> <p>5 have a risk that's not statistically</p> <p>6 significant, you don't automatically say</p> <p>7 you've identified a risk factor for</p> <p>8 something. You would say I found a</p> <p>9 non-significant elevation or a</p> <p>10 non-significant decrease.</p> <p>11 But that's not the same</p> <p>12 thing as finding a statistically</p> <p>13 significant one.</p> <p>14 Q. But even a non-statistically</p> <p>15 significant increased risk is still an</p> <p>16 increased point estimate, correct?</p> <p>17 A. An increased?</p> <p>18 Q. Point estimate.</p> <p>19 A. Well, the point estimate can</p> <p>20 be elevated. But it's not the same as</p> <p>21 saying that you've identified a risk.</p> <p>22 Q. And even a non-statistically</p> <p>23 significant increased risk is still an</p> <p>24 increased risk?</p>	<p style="text-align: right;">Page 141</p> <p>1 your report, correct?</p> <p>2 A. Did I rely or did I report</p> <p>3 on?</p> <p>4 Q. You report on.</p> <p>5 A. Well, sure, I tried to</p> <p>6 include what I find from the actual</p> <p>7 studies. Like, I'm trying to include the</p> <p>8 information and summarize it.</p> <p>9 Q. So when you report that the</p> <p>10 Mansouri study found a protective effect</p> <p>11 for liver cancer in women, that was</p> <p>12 non-statistically significant, correct?</p> <p>13 A. That's exactly right.</p> <p>14 Q. And yet you still reported</p> <p>15 that finding; you didn't say there's no</p> <p>16 risk of liver cancer, you said protective</p> <p>17 risk -- or protective of liver cancer --</p> <p>18 A. That's --</p> <p>19 Q. -- correct?</p> <p>20 A. That's the direction that it</p> <p>21 points. It was 0.9, which is less than</p> <p>22 1. So it's -- it's even stronger</p> <p>23 evidence against there being a value</p> <p>24 that's above 1.</p>

<p style="text-align: right;">Page 142</p> <p>1 But I wouldn't -- you know, 2 if you ask the next question, about 3 whether I would, then, interpret that as 4 that women should start taking this to 5 protect themselves against the risk of 6 liver cancer, I wouldn't, and, in part, 7 because that is not a statistically 8 significant increase. 9 But that -- 10 Q. So would -- 11 A. I'm sorry. 12 Q. Sorry. I didn't mean to 13 interrupt you. 14 A. I'm just saying that would 15 only be one of many reasons that I 16 wouldn't interpret it as truly finding 17 that this -- that administration of that 18 drug would be protective. 19 But -- but part of the 20 information would be a non-statistically 21 significant decrease below 1. 22 Q. When you use the terminology 23 "protective," what would be your 24 terminology on the other side, above 1?</p>	<p style="text-align: right;">Page 144</p> <p>1 those who use both exposed -- are both 2 exposed to contaminated product and 3 uncontaminated product, it doesn't report 4 that -- that increased risk, correct -- 5 or that risk? 6 A. I think so. But it's 7 testing my memory. But I think what 8 you're saying sounds right. 9 Q. Doctor, what are -- what are 10 multiplicity analyses? 11 A. It's a little off from the 12 term I would use. 13 But multiple comparison 14 analysis, is that -- does that sound like 15 what you're asking me? 16 Q. It does. 17 What's the terminology you 18 would use since -- 19 A. Yeah. I would take -- I'm 20 sorry. 21 I would just say accounting 22 for multiple comparisons. 23 Q. Okay. And what would the 24 FDR test be in terms of comparing for</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Elevated. 2 Q. Elevated. Okay. 3 So, Doctor, would you agree, 4 then, that a -- for example, a 1.2 5 non-statistically significant result 6 would be an elevated risk? 7 A. So the -- yeah. The 8 estimate is elevated, that's right, 9 above 1. 10 Q. And, Doctor, in the Mansouri 11 study where you report the protective 12 findings for women for liver cancer, they 13 found an even higher elevated risk for 14 liver cancer in men, correct? 15 A. Yeah. When you separate men 16 from women, that's right. Because their 17 initial analysis pooled the two, so it's 18 a weighted average of both men and women 19 together. 20 So for the women's value to 21 go down, the men's value has to go up. 22 Q. Doctor, the Mansouri study 23 doesn't report the increased risk of 24 liver cancer in men when mixed users,</p>	<p style="text-align: right;">Page 145</p> <p>1 multiple comparisons? 2 A. There's different 3 techniques. And you're referring to a 4 false discovery rate, right. 5 So it's -- but there's 6 different techniques to be used in order 7 to change the level of significance 8 you're willing to accept by accounting 9 for the number of different comparisons 10 that you're making. 11 Q. There's different sections, 12 one of those would be false discovery 13 rate. Another would be Bonferroni, 14 correct? 15 A. Bonferroni is an example. 16 It accounts for a false discovery rate. 17 I just -- 18 Q. More -- 19 A. I think the general -- 20 Q. Go ahead. 21 A. I'm sorry. I apologize. 22 I just -- I just think the 23 general concept is you're trying to 24 reduce the risk of false discovery. And</p>

<p style="text-align: right;">Page 146</p> <p>1 so Bonferroni is one technique that can 2 be used. 3 Q. But there's also a technique 4 called FDR, correct? 5 A. No, I don't think so. I 6 mean, to me, that's -- that's the 7 concept, right. 8 I think one of these studies 9 used -- there was a technique by Hochberg 10 and another colleague and -- which was 11 another way to do the same thing. Like, 12 there isn't just one way to do it. 13 But the concept is false 14 discovery which means, you know, you've 15 done so many tests that just by chance 16 you're going to pop up positive ones that 17 really aren't telling you the truth. 18 So you want to limit the 19 chance of that happening by lowering the 20 risk of false discovery. 21 Q. Doctor, the Bonferroni 22 technique is rarely used in 23 epidemiological studies assessing safety 24 risk, correct?</p>	<p style="text-align: right;">Page 148</p> <p>1 A. I've not seen a paper that 2 says that. I haven't sought one. The 3 only -- the only information I have is 4 from Dr. Sawyer saying that. And I don't 5 know that he's correct. 6 Q. Doctor, have you analyzed 7 whether or not the Bonferroni technique 8 is rarely used in epidemiological studies 9 assessing safety risk in the past 20 10 years? 11 A. Same kind of answer. I'm 12 just -- I don't -- I don't know where I 13 would go to find out what the prevalence 14 is of the use of Bonferroni. 15 But I'm not aware that the 16 qualifier "rare" would be true. I just 17 don't know. 18 Q. Doctor, do you know whether 19 or not other experts in this valsartan 20 litigation have testified that the 21 Bonferroni technique is rarely used in 22 epidemiological studies assessing safety 23 risk? 24 A. I don't know. I don't know</p>
<p style="text-align: right;">Page 147</p> <p>1 A. So I saw Dr. Sawyer say 2 that. But I don't know that he's 3 correct. 4 I mean, I've used it in 5 studies. I don't know if it's fair to 6 characterize it as rare. I mean, when I 7 was initially, you know, being trained in 8 biostatistics, it was really a very 9 common one for people to describe. 10 And I have no idea what, you 11 know, the prevalence of the use is. But 12 it's still -- it's still out there to be 13 used. 14 Q. Doctor, have you reviewed 15 any papers that suggest the Bonferroni 16 technique is inappropriate to use when 17 assessing safety risk? 18 A. I don't know how it would 19 pertain particularly to safety risk. 20 Q. And have you reviewed any 21 papers that suggest that the Bonferroni 22 technique is rarely used in 23 epidemiological studies assessing safety 24 risk in the past 20 years?</p>	<p style="text-align: right;">Page 149</p> <p>1 the testimony of other -- other experts. 2 Q. Are you aware of whether or 3 not other experts on behalf of defendants 4 have testified that the Bonferroni 5 technique is rarely used in 6 epidemiological studies assessing safety 7 risk? 8 A. So -- 9 ATTORNEY DAVIDSON: 10 Objection. Asked and answered. 11 THE WITNESS: Yeah. Sorry. 12 I still don't have awareness 13 of what they've testified to. 14 BY ATTORNEY NIGH: 15 Q. Do you have any reason to 16 disagree with them? 17 A. I mean, if -- I don't have 18 any reason to disagree in the sense that 19 if they can cite something, I would be 20 happy to look at it. But it's not 21 something I'm aware of I. 22 I mean, my colleagues still 23 talk about using it, you know. So I 24 don't know where the rareness idea comes</p>

<p style="text-align: right;">Page 150</p> <p>1 from.</p> <p>2 Q. When you say your colleagues</p> <p>3 still talk about using it, they talk</p> <p>4 about using it in assessing safety risk</p> <p>5 in epidemiological studies?</p> <p>6 A. No. So here we're talking</p> <p>7 about, I guess, a pharmacoepidemiology</p> <p>8 study.</p> <p>9 So I don't know about the</p> <p>10 state of, you know, what the preferred</p> <p>11 false discovery rate techniques are for</p> <p>12 safety studies.</p> <p>13 But I'm talking about</p> <p>14 epidemiologic studies in general where</p> <p>15 the concept is generally the same, right.</p> <p>16 You do a lot of tests, you're going to</p> <p>17 get a lot of wrong answers. And you want</p> <p>18 to minimize the chance that that's</p> <p>19 happening.</p> <p>20 Q. Bonferroni is assessing the</p> <p>21 chances of whether or not one or more of</p> <p>22 the results in a study may have been --</p> <p>23 may have led to a false discovery or a</p> <p>24 false positive rate, correct?</p>	<p style="text-align: right;">Page 152</p> <p>1 But I don't know. I mean, I</p> <p>2 don't know what opinion we're -- we're</p> <p>3 trying to augment here about something</p> <p>4 about safety.</p> <p>5 I mean, I guess if the</p> <p>6 issue -- if the issue is about getting</p> <p>7 the truth, then you ought to take some</p> <p>8 care. If you don't care about the truth</p> <p>9 and you're willing to have a lot of false</p> <p>10 positives, and that somehow feeds into</p> <p>11 some idea about safety, I guess go for</p> <p>12 it, right.</p> <p>13 But it's -- it doesn't -- it</p> <p>14 certainly doesn't enhance your ability to</p> <p>15 find the truth.</p> <p>16 Q. So you don't believe that</p> <p>17 the way in which you find a Bonferroni</p> <p>18 score is to divide the P value divided by</p> <p>19 the number of outcomes assessed in the</p> <p>20 study?</p> <p>21 A. I just don't -- I don't</p> <p>22 remember. I don't -- I don't conduct</p> <p>23 that part. Like, I work with</p> <p>24 biostatisticians in our studies. And so</p>
<p style="text-align: right;">Page 151</p> <p>1 A. I don't accept that, no. I</p> <p>2 think -- I think it's a technique that's</p> <p>3 used to reduce the risk of that.</p> <p>4 And so that what it does is</p> <p>5 it helps you to create a P value. So</p> <p>6 instead of the conventional .05, which is</p> <p>7 the 5 percent Type I error rate that</p> <p>8 you're baking into your study, it makes</p> <p>9 it something much smaller than .05. It's</p> <p>10 not just one specific number.</p> <p>11 Q. So you think -- do you think</p> <p>12 it would be appropriate, in assessing</p> <p>13 safety risk, if there are 100 outcomes</p> <p>14 analyzed in an epidemiological study that</p> <p>15 you would divide the P value of .05</p> <p>16 divided by 100?</p> <p>17 A. I don't think that's the</p> <p>18 right technique. I don't think it's</p> <p>19 simple math like that.</p> <p>20 There's -- there's other</p> <p>21 weighting that goes into it. And I don't</p> <p>22 conduct those analyses myself. So I</p> <p>23 can't describe to you in detail how the</p> <p>24 technique is actually applied.</p>	<p style="text-align: right;">Page 153</p> <p>1 I don't -- that's not part of my work is</p> <p>2 to conduct it.</p> <p>3 ATTORNEY DAVIDSON: A good</p> <p>4 time for a break?</p> <p>5 ATTORNEY NIGH: I think so.</p> <p>6 ATTORNEY DAVIDSON: You just</p> <p>7 seem to be --</p> <p>8 ATTORNEY NIGH: No, now is</p> <p>9 no problem. I am moving to</p> <p>10 something different.</p> <p>11 So let's take a ten-minute</p> <p>12 break.</p> <p>13 VIDEO TECHNICIAN: Off the</p> <p>14 record, 1:43.</p> <p>15 - - -</p> <p>16 (Whereupon, a brief recess</p> <p>17 was taken.)</p> <p>18 - - -</p> <p>19 VIDEO TECHNICIAN: We are</p> <p>20 back on the record at 2:00 p.m.</p> <p>21 ATTORNEY NIGH: Doctor, I do</p> <p>22 not have any other questions.</p> <p>23 Thank you.</p> <p>24 THE WITNESS: Thank you.</p>

<p style="text-align: right;">Page 154</p> <p>1 ATTORNEY DAVIDSON: Sorry. 2 I don't think I heard you. 3 ATTORNEY NIGH: I don't have 4 any other questions. 5 ATTORNEY DAVIDSON: Okay. 6 Let's just take a five-minute 7 break. I think I might have one 8 question, max. 9 VIDEO TECHNICIAN: Off the 10 record, 2:00 p.m. 11 - - - 12 (Whereupon, a brief recess 13 was taken.) 14 - - - 15 VIDEO TECHNICIAN: We are 16 back on the record at 2:02 p.m. 17 - - - 18 EXAMINATION 19 - - - 20 BY ATTORNEY DAVIDSON: 21 Q. Dr. Diette, you were asked a 22 couple of questions earlier today about 23 my client, ZHP. 24 Do you generally understand</p>	<p style="text-align: right;">Page 156</p> <p>1 CERTIFICATE 2 3 4 I, Amanda Maslynsky-Miller, Certified 5 Realtime Reporter, do hereby certify that 6 prior to the commencement of the examination, 7 GREGORY DIETTE, Ph.D., was remotely sworn by 8 me to testify to the truth, the whole truth 9 and nothing but the truth. 10 11 I DO FURTHER CERTIFY that the foregoing is a 12 verbatim transcript of the testimony as taken 13 stenographically by me at the time, place and 14 on the date hereinbefore set forth, to the 15 best of my ability. 16 17 I DO FURTHER CERTIFY that I am neither a 18 relative nor employee nor attorney nor 19 counsel of any of the parties to this action, 20 and that I am neither a relative nor employee 21 of such attorney or counsel, and that I am 22 not financially interested in the action. 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000</p>
<p style="text-align: right;">Page 155</p> <p>1 what ZHP's role is in this lawsuit? 2 A. Well, yeah, I mean, I know 3 they're -- they're a pharmaceutical 4 company, obviously, from -- from China. 5 And I understand one of 6 their products is valsartan that was 7 contaminated with NDMA. 8 ATTORNEY DAVIDSON: I don't 9 have any other questions. 10 ATTORNEY NIGH: Okay. No 11 questions here. Thank you. 12 VIDEO TECHNICIAN: That 13 concludes today's deposition. The 14 time is 2:03 p.m. 15 - - - 16 (Whereupon, the deposition 17 concluded at 2:03 p.m.) 18 - - - 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 157</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason 6 in the appropriate space on the errata 7 sheet for any corrections that are made. 8 After doing so, please sign 9 the errata sheet and date it. 10 You are signing same subject 11 to the changes you have noted on the 12 errata sheet, which will be attached to 13 your deposition. 14 It is imperative that you 15 return the original errata sheet to the 16 deposing attorney within thirty (30) days 17 of receipt of the deposition transcript 18 by you. If you fail to do so, the 19 deposition transcript may be deemed to be 20 accurate and may be used in court. 21 22 23 24</p>

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1	ACKNOWLEDGMENT OF DEPONENT		
2	I, _____, do		
3	hereby certify that I have read the		
4	foregoing pages, 1 - 155, and that the		
5	same is a correct transcription of the		
6	answers given by me to the questions		
7	therein propounded, except for the		
8	corrections or changes in form or		
9	substance, if any, noted in the attached		
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11	_____		
12	GREGORY DIETTE, Ph.D. DATE		
13	Subscribed and sworn		
14	to before me this		
15	_____ day of _____, 20____.		
16	My commission expires: _____		
17	_____		
18	Notary Public		
19			
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[& - accurate]

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